STATE OF INDIANA)
) SS:
COUNTY OF DELAWARE)

IN THE DELAWARE COUNTY SUPERIOR COURT

CRAIG DUNN and PHILIP WILEY, et al.,)
Plaintiffs,)
)
-v-) CAUSE NO.
) 18D01-9305-CT-06
RJR NABISCO HOLDINGS CORPORATIONS, et al.,)
Defendants.)

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MR. CASSELL: All rise.
THE COURT: Be seated. Good morning, ladies and gentlemen. Congratulations. I see you all made it this morning.
Good morning, Counsel.
ALL: Good morning.
THE COURT: Is the witness here?
MR. FURR: He is, Your Honor.
THE COURT: All right.
DEFENDANTS' WITNESS, PAUL LEVY, SWORN
THE COURT: Have a seat, please. Would you state your name again, please.
THE WITNESS: Paul Levy.
THE COURT: All right. We are on cross-examination, Mr. Patrick.
MR. PATRICK: Thank you, Your Honor.

CROSS-EXAMINATION
BY MR. PATRICK:
Q Good morning, Dr. Levy.
A Morning, Mr. Patrick.
Q Dr. Levy, I believe you told us yesterday that you did some research of the medical literature and that you attempted to obtain

all of the articles that have discussed the hazards of environmental tobacco smoke. Is that correct?
A And lung cancer.
Q And lung cancer. Is that correct?
A Yes, that's correct.
Q Let me show you an article.

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A Sure.
MR. PATRICK: Your Honor.
Q Dr. Levy, when you began your research of the medical literature, did you -- first of all, what is the British Medical Journal?
A It's what it says it is. It's a British medical journal. It's, I think, one of the two major medical journals reporting general medical literature, medical -- general medical research, sort of that and Lancet, maybe comparable to the Journal of the American Medical Association and the New England Journal.
Q So it's a journal that investigators, scientific investigators, would generally rely on when doing medical searches.
A It's one of the better peer-reviewed journals.

Q All right. And I believe you stated yesterday, you began your investigation in September of 1997; is that correct?
A September or October, or October -- I forgot the exact date.
Q All right. This article came out in October, on October 18, 1997, and it is entitled, "The Accumulated Evidence on Lung Cancer and Environmental Tobacco Smoke" by Drs. Hackshaw, Law, and Wald. Are you familiar with this article?
A I think -- I think it's probably in the data -- I think I did look at it. It's not an original article -- it's not -- it's a review article. I was basically concerned with the original studies. But, yes, I think I looked at it.
Q All right. It contains what you did basically. It's a meta-analysis or a pooling of all of the data contained from previous articles published to date, is it not?
A Let me look through before I answer your question, okay? Okay. They looked at 37 articles. There are 46 available. I've

looked at the 46, but I focused on primarily, as I've said in my direct, the U.S. spousal and the U.S. workplace studies.
Q I understand.
A But it looks as if that's -- he looked at 37 articles that were available, presumably, when he had done his work, or they had done this work or she had done her work. I don't know the authors.
Q Right.
MR. PATRICK: Your Honor, if I may display this on the screen so we can look at the conclusion?
THE COURT: Any objection?
MR. FURR: Well, I would, Your Honor. I mean, if he's established it's a

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learned treatise, the doctor is being cross-examined with it, but I don't believe that means he can display it on the screen and read it to the jury that way.

THE COURT: Actually, he can ask him about the treatise. The doctor said it was a learned treatise in Britain, I believe. He can ask him about it. It is not, ladies and gentlemen, introduced in

evidence. It goes to the weight to be given to the doctor's testimony. You may display that.

MR. PATRICK: Thank you, Your Honor.

If you can bring it up to the conclusion. Up a little more.

Q Now, Doctor, if you can see that -- maybe you can make reference to the copy that you have. Wouldn't you agree that when the doctors in this article, the authors of this article, looked at all of the evidence of environmental tobacco smoke and its relationship to lung cancer, that they concluded that the epidemiological and biochemical evidence on exposure to environmental tobacco smoke, with the supporting evidence of tobacco-specific carcinogens in the blood and urine of nonsmokers exposed to environmental tobacco smoke, provides compelling confirmation that breathing other people's tobacco smoke is a cause of lung cancer?

A That's what they're saying. I can't see it that well. Can you tell me where it is in

the -- sorry to be so slow.

Q Very first page. Look to the left-hand side, and then go to the bottom and that's where the conclusion is.

A Oh, it's in the abstract, okay.

Q Right.

A I agree that's what they concluded, that's what they said. Again, they didn't do original studies. This is another review of the literature and other meta-analysis, and to evaluate their findings against what I concluded from my own findings, I'd have to see exactly which studies they looked at, how they -- how they did their meta-analysis, what they corrected for and what they did not correct for, whether they corrected for bias and other types of misclassification, and I looked at my -- I presented how I looked at the studies that I looked at and came to different conclusions.

Q I understand.

A Okay.

MR. PATRICK: Can you bring it down a little bit to the -- down some more.

Q In fact, there's a monitor behind you that

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you might be able to look at.
A Oh, I'm sorry, yes, there is.
Q If you look, first of all, at the objectives of the study, it says "to estimate the risk of lung cancer in lifelong nonsmokers exposed to environmental tobacco smoke."
Do you see that?
A Yes.
Q And then, "The design analysis of 37 published epidemiological studies of the risk of lung cancer (4,626 cases) in nonsmokers who did and did not live with a smoker. The risk estimate was compared with that from linear extrapolation of the risk in smokers using seven studies of biochemical markers of tobacco smoke intake."
Do you see how the design was set up of this study?
A Let me look at it.
Q See that?
A Yes.
Q And you see under the results, "The excess risk of lung cancer was 24 percent (to 95 percent confidence interval, 13 percent to

36 percent)." So they found a relative risk of 1.24, or 24 percent, and I believe you talked about that 95 percent confidence interval yesterday, did you not?
A Yes.
Q All right. And 95 percent is what you as epidemiologists normally and standardly use as the confidence interval, or the baseline that you use to make these analyses; isn't that correct?
A Yes. That's correct.
Q And these authors, these people who published in this journal, use the 95 percent confidence interval.
A They used a 95 percent confidence interval, and they state their findings. Again, if you're asking me to critique their findings, they're certainly different from what I have found possibly -- probably using a subset of -- a set of studies that didn't quite exactly coincide with theirs, and you saw what I did and that I've got different -- that I obtained different, somewhat different findings.
I notice the relative risk is very

similar to what EPA got. From the looks of their design, they didn't control for misclassification. But in all fairness to them, I can't critique it without -- if that's what you're asking me to do -- without really reading it and absorb it.
Q Well, if you would look -- if you could turn

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over to page 983, Doctor.
A Okay.
Q All right. You see that section that says "Misclassification Bias"?
A Is it in a table or -- okay.
Q It's on the right-hand side.
A 983?
Q 983.
A Oh, okay.
Q You see there's a section on misclassification bias?
A Yes, I see it. Do you want me to read it?
Q Would you agree that if you looked at -- well, why don't you look at it. My question to you is: Doesn't this article indicate that they did take the misclassification bias into account in coming up with their results?

A Okay. Without taking too much time with the Court.
Q Maybe we can move, get to this in another fashion.
A Yes. Can I say something about it?
Q Certainly.
A They considered misclassification. They used a method, apparently, for dealing with misclassification that looks similar to the methods that, or in the same generic class of methods that have been used by the EPA, and also by Peter Lee and others that have also dealt with this problem. Lee is, in his basic paper, Lee and Foray, in which he also does a review of other methods, is a good copy, hence, of what's available.
You and I could do the same type of analysis. We could use the same generic method, we can put in slightly different numbers, make slightly different assumptions, and come up with entirely different estimated rates of misclassification.
He used some method, obtained some -- or they obtained some estimates of

misclassification. I can't evaluate them against Lee or what I would consider reasonable at this point. And they came up with findings that were different, certainly, a different conclusion -- reached -- came to a different conclusion than mine. Is that fair?
Q That's fair. That's fair.
A Yeah.
Q And Doctor, if you would turn to page 985.
MR. PATRICK: Can we get on the board the bottom right-hand column, please, or on the screen.
Q Doctor, let me try to speed this up a little bit. Just go to the key messages, and see if you agree or disagree with what the

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authors had to say. Now, we're looking at page --
A Did you say 989?
Q 985, excuse me.
A Not all these pages have numbers.
Q Maybe you can look at mine.
A Yes, I got it. Sorry. And I lost it. Okay.
Q First conclusion, "A woman who has never

smoked has an estimated 24 percent greater risk of lung cancer if she lives with a smoker." That's what the author is stating, concluded in their article; correct?
A That's what they concluded.
Q And they state that "Neither bias" -- and you talked about bias yesterday; correct?
A Correct.
Q -- "nor confounding" -- you talked about confounding -- "accounted for the association." Correct?
A That's what they're saying.
Q "There is a dose-response relation between a nonsmoker's risk of lung cancer and the number of cigarettes and years of exposure to the smoker." Correct?
A That's -- that's what their conclusion is. I don't agree with it, but yes, that's what they're saying.
Q All right. And they also say, "The increased risk was consistent with that expected from extrapolation of the risk in smokers using biochemical markers."
Do you see that?
A I'm seeing what they're saying. That's an

area that's also controversial, the extent with which they can extrapolate and use misclassification. But yes, that's what they've looked at and what they're saying.
Q All right. You as epidemiologists, use a set of criteria, do you not, to assess or judge causality, whether or not a statistical association is enough to say an agent causes a disease, or specifically a chronic disease as in this case?
A Yes.
Q And you're familiar with a textbook entitled, "The Foundations of Epidemiology" by Lillenfeld, are you not?
A Can I see it?
Q Sure. You knew -- did you know Dr. Abraham Lillenfeld?
A Very well. He was one of my teachers at Hopkins.
Q And do you know his son, Dr. David Lillenfeld?
A I don't know him quite so well, but I know who he is and I've met him.
Q All right. Did you know that Dr. David Lillenfeld -- Dr. Abraham Lillenfeld is no

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longer alive; correct?
A Correct.
Q His son revised his father's textbook which is one of the leading textbooks on epidemiology; correct?
A It's out there. I'm not sure it's one of the -- the original Lillenfeld was. I'm not sure how this -- this is by Lillenfeld and Paul Stolley, who is at the University of Pennsylvania. I'm looking for the date on it. I'm not sure it's -- I'm not sure you got the most recent edition.
Q Okay. Well, let me just ask you about the principles. In order to assess causality, you look -- you talked about this yesterday -- the strength of the association; correct?
A Correct.
Q These are what is referred to in epidemiology as the Hill, Bradford Hill?
A They're attributed to Bradford Hill. It may not be correct that he originated them, but yes, they're called the Hill's postulates.
Q Strength of the association, consistency of the observed association, specificity of the

association, temporal sequence of events, dose-response relationship, and also there's one called biological plausibility of the observed association. Correct?
A Yeah. There may be some others, and some of them are more emphasized than others, but that's out there.
Q Let's talk a minute about biological plausibility. And there's also another one, experimental evidence; would that be correct?
A No.
Q No?
A That would go along with biological plausibility.
Q Okay.
A I don't think experimental evidence is one of them.
Q Now, one, if you're trying to assess biological plausibility, you want to look to see whether or not there's any evidence that the specific agent, as in this case, environmental tobacco smoke, or what is contained in environmental tobacco smoke, somehow it makes biological sense that it

will get into the body. Correct?
A Yes.
Q And in your review of the medical literature --
MR. PATRICK: Your Honor, may I approach?
THE COURT: Yes.

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Q -- did you -- in your review, did you come across an article on an investigator by the name of Steven Hecht, who specifically found carcinogens in hospital workers who were exposed to environmental tobacco smoke?
A What are you -- I'm not sure where this is, what you're showing me.
Q This is an article, Doctor, this is an article I think we discussed -- I don't think you and I discussed, but it's been discussed in court, dated March 1998, Hecht, Parsons, Carmella?
A Okay, okay. I didn't realize it was in back of the thing you showed. Okay. I got it.
Q All right. Are you familiar with this article?
A No, I am not familiar with that article. I'm not an expert on biomarkers for ETS. I

think there were other witnesses that have -- that are dealing with this. I basically dealt with what was found in the human epidemiological studies and approached my review from that -- from that standpoint.
Q So that if in -- and I'm going back to this article that appeared in the British Medical Journal. If, in fact, they state that tobacco-specific carcinogens are found in the blood and urine of nonsmokers exposed to environmental tobacco smoke, and they used that to come to the conclusion that ETS is a cause of cancer, that is not an area that you have concentrated on; correct?
A Correct.
Q You're here just to talk about the statistical associations that are found in the medical studies; correct?
A Whether -- about the statistical associations, whether -- yeah, what I had talked about. The associations between the exposures and the disease, whether the strength of them, whether they were statistically significant, whether the biases were accounted for. If all of this

was not present, then I was not able to conclude that there was evidence from the human studies. The plausibility was not dealt with. I think that's separate, even in the EPA criteria. One looks at, for a Class A -- for classification of a substance as a Class A carcinogen, one has to have evidence from human studies. If that's sufficient, in spite of whatever anything else is, it's classified as a grade A -- a Class A carcinogen. If not, it isn't.
Then there's another class, other evidence, and I assume evidence, as you're mentioning, experimental evidence, biomarkers, that's separate. And I believe -- and I may be wrong -- that if the

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human studies are not conclusive, then a substance cannot be classified as a class A carcinogen by the EPA criteria.

Q All right. So if I can understand, you have not looked at the literature on biochemical markers or the presence of ETS in the bloodstream of individuals; correct?

A Or the presence of what in --

Q Well, the breakdown elements. Let's say the

carcinogens contained in environmental tobacco smoke, if they're in the blood of people that have been exposed to ETS, you haven't looked at that literature.

A No, I have not, not in a systematic way, and that's not part of my expertise. I did look at some of the material on cotinine in the urine as a marker of -- as a marker of tobacco, viewed active smoking as a potential marker of tobacco for active smoking for misclassification.

Q All right. And if there are studies where mice are exposed to environmental tobacco smoke in smoking chambers and they develop cancer, you haven't looked at that particular evidence either?

A If there are such studies, and I have not looked at them, and I, of course, can't say whether there are such studies; and if they are, what's the validity and reliability of them.

Q Doctor, let's move to the final -- I'm going to try to shorten this up so we can get you out of here.

A It's no better in Chicago than here, so --

Q I think it's a little bit worse.

If you look back at this article that appeared in the British Medical Journal just for a second, and if you -- the first page is 980, the second page is 981, and the third page is 982, and if you look under the section that, it says "Results," it says seven of the studies that these authors looked at showed a significant excess risk. Do you see where they make that statement?

A Yes.

Q I take it you would disagree, based on your direct testimony, that seven of the -- and they say 39, I believe it was 37, 37 of the articles showed a significant excess risk?

A Yes. I mean, I'm not disagreeing -- I'm not saying -- obviously, if they said seven of the ones they looked at were significant, I'm not disputing that. This looks like a reputable article. However, remember, they looked at a different set from mine, from the one I looked at. I looked at U.S. studies, I looked at U.S. spousal, U.S. workplace, so it's not unlikely that -- okay. I think they included foreign

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studies.
Q Using your chart, if you look -- you got -- you had this yesterday?
A Okay. I can't see it.
Q All right. Maybe I can borrow --
MR. FURR: Sure. What one do you need?
A If you just give me a quick look, I can remember it.
Q If you look at your chart that we looked at yesterday, U.S. female workplace epidemiological studies, can you tell me how these individuals were exposed to environmental tobacco smoke in these studies? If --
A In the work -- no. Other than in the workplace? No.
Q Right.
A No.
Q I mean, do you know if they were exposed in restaurants or they were exposed in offices or they were exposed in hospitals? Do you know how they were exposed?
A You mean where they worked?
Q Where they worked.

A No, it didn't say.
Q And the amount of smoke they breathed?
A No, I think none of the studies, workplaces or spousal, actually measure the amount of smoke which is why I dispute the term dose response or evident trend when it's used, but, no, we all have background ETS. I assume these people have. But these, I assume, that these were people that were exposed in the workplace but not the home.
Q So these four studies that are less than 1.0, they could have been studies, as far as you know, of situations where I would sit at an office desk, and let's say Mr. Westbrook would be over there smoking a cigarette once every eight hours, for that matter.
A Once what?
Q Once every eight hours.
A I would have to look at how each particular article, those are four different articles, how they measured smoke and how they asked that particular question. I can't -- you know, I can't answer that yes or no at the moment. One would have to look at the questions and classify how the questions

were written. But all of these are peer-reviewed articles.
Q You would agree that with tobacco smoke, either mainstream smoking or environmental tobacco smoke, there is a dose-response relationship; correct?
A I would agree with it with active smoking,

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there appears to be a dose response. With ETS, there -- since one doesn't measure the amount of environmental tobacco smoke exactly, for some of the reasons you just gave a moment ago, what you have is a trend in some of the articles, and it's generally the last figure that's elevated. So -- and I can't pinpoint the particular studies at the moment, but you could have -- if I'm talking to the jury -- you could have a point at a no dose, a point slightly higher here at a slightly higher dose; this is lung cancer incidence, say. Then the third point could go down, and that fourth point, which might be based on very much fewer subjects and also subject to more confounding and misclassification, might be the one that's driving the thing up.

So you don't always get a pure, straight, what we call a monotonic line in ETS. You get scattered, but the last point higher, and so you get a significant, what some of the authors have called a dose response, which is really a trend.

Q All right. I guess what I'm asking, and let's just use mainstream smoking as an example, you have a greater risk if you smoke two packs of cigarettes a day than if you smoke two cigarettes a day?

A Active smoking, yes.

Q Correct.

A Of lung cancer.

Q Of lung cancer. And if ETS is a cause of lung cancer, the more you inhale of ETS, the larger the dose, the greater your risk is going to be.

A Not necessarily. First you have to assume that it is a risk factor for lung cancer, and that's a conclusion I haven't come to. Then you have to assume that there is a dose response that -- that the carcinogen -- the carcinogenesis works in such a way that the more you're exposed, the more you -- the

more you get. Some carcinogens don't work that way. So I can't answer your question yes or no.

Q Well, assume that the Environmental Protection Agency and the Surgeon General and the National Cancer Institute and the authors of this paper are correct and that ETS is a cause of cancer. If you make that assumption that ETS causes cancer, would you not agree then that with carcinogens, and with ETS as a carcinogen, the more you breathe, the greater the risk?

A Not necessarily, because I don't know how it works.

Q So if you look back at page 985 of this paper that was printed, or published in

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October of 1997, and if it stated that there is a dose-response relation between a nonsmoker's risk of lung cancer and the number of cigarettes and years of exposure to the smoker, you would disagree with their conclusion. Correct?

A Yes, I would. Just -- just on the basis of what they're calling it.

MR. PATRICK: Bear with me a moment.

THE WITNESS: Sure.

Q In this case, when you were preparing for your testimony, you didn't look at any of the specific pieces of evidence as they pertained to Mrs. Wiley, did you?

A I don't think I did. I don't think so. Okay. Could you give me some examples?

Q Well, you don't know whether or not you've -- you haven't looked at any DNA test to see whether or not --

A No.

Q -- her DNA were mutated by ETS?

A No, sir.

Q And you haven't looked at any of the documents from the internal corporate documents of the tobacco companies, have you?

A No, I don't believe I have.

Q You don't know what they -- what the investigators at the tobacco companies may have been doing in doing their own research on environmental tobacco smoke, are you? You're not familiar with that?

A No, I don't think I am. No. No.

Q You mentioned a Peter Lee. Do you know Peter Lee?

A I know who he is. I don't -- I've never met the man.

Q Do you know that he is a consultant for the tobacco companies in Great Britain?

A Yes, I know -- well, I know that, in his peer-reviewed articles in statistics and medicine, he lists up front that he's supported by some tobacco organization, and I'm not familiar with what it is. I would assume it would probably be the British tobacco -- either their -- if they have something, some research organization, or the tobacco companies themselves, but I don't -- I don't know exactly what it is. But, yes, he's -- he's supported, and he lists it up front that he's supported by tobacco.

MR. PATRICK: Bear with me. Dr. Levy, I hope you make it back okay to Chicago, the snow begins to abate a little bit. Nice to see you.

THE WITNESS: Good to see you, Mr. Patrick.

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MR. PATRICK: Thank you, Your Honor, I don't have any further questions.
THE COURT: Thank you, Mr. Patrick. Mr. Furr, any redirect?
MR. FURR: Yes, I do, Your Honor.

REDIRECT EXAMINATION
BY MR. FURR:

Q Good morning, Dr. Levy.
A Morning, Mr. Furr.
Q Dr. Levy, in preparing to testify in this case, did I ask you to review the epidemiologic studies of active smoking and lung cancer?
A No, you didn't.
Q And did I ask you to come here and provide any opinions with respect to any relationship between active smoking and lung cancer?
A No, you didn't.
Q Mr. Patrick asked you some questions about whether or not you had ever conducted any original research on tobacco smoke and cancer. Do you recall that?
A Yes, I do.
Q Dr. Levy, you have been involved in

epidemiologic studies of cancer, haven't you?
A Yes.
Q And have you also been involved in epidemiologic studies involving environmental exposures?
A Yes, I have.
Q Dr. Levy, I'm going to ask you not to be modest on this question. I want to ask you whether or not there's any doubt in your mind that you have the expertise to evaluate the epidemiologic studies of environmental tobacco smoke and lung cancer?
A I feel that I do.
Q Mr. Patrick asked you several questions about different organizations that have issued statements involving their views of what the data show with respect to environmental tobacco smoke and lung cancer; is that correct?
A That's correct.
Q Dr. Levy, as a scientist and a researcher, when you're addressing an issue like this, do you rely upon the conclusions of others, or do you go and obtain the data and analyze

them for yourself?
A I'm much more comfortable looking at the data myself, fooling around with the numbers. Numbers are my life. That's what I deal with.
Q And why do you prefer looking at the data yourself than relying on the conclusions of

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others?
A Because I don't know on what their conclusions are based, I don't know whether they've looked at their data in a valid way. I prefer, especially in situations like this, knowing what I'm talking about, looking at the -- doing my own analysis when that's possible.
Q And in this case, you did in your analysis rather than rely upon the conclusions of others, I take it?
A Yes.
Q Dr. Levy, you were asked some questions about a report issued by the California EPA. Do you recall that?
A Yes.
Q Was the California EPA report an original study of the question of environmental

tobacco smoke and lung cancer or was it a review?
A It was a review.
Q Do you recall when that report was issued?
A 1997. I don't know when.
Q So at least the California EPA thought that the question of environmental tobacco smoke and lung cancer required further review in 1997, didn't it?
A Apparently.
Q Now, you testified that the California EPA would have looked at approximately the same set of studies that you looked at; correct?
A I haven't -- again, I haven't reviewed it thoroughly, but yes, they -- the same studies were available for their report as the ones I had looked at.
Q As Mr. Patrick pointed out, the California EPA reached certain conclusions about what the studies of workplace exposure to environmental tobacco smoke showed, didn't it?
A Yes.
Q Now, when you reached your conclusions, you told us yesterday that you conducted a

meta-analysis of the U.S. workplace ETS studies, and that that meta-analysis showed no evidence of an increased risk, didn't you?
A Correct.
Q Did the California EPA conduct a meta-analysis of the workplace studies?
A I don't believe they did.
Q Dr. Levy, you recall that yesterday Mr. Patrick asked you some questions about the Fontham study?
A Yes, I do.
Q Now, when you conducted your -- you told us that the first thing that you did in your analysis was that you attempted to make sure that you had obtained all data before you

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began analyzing; correct?
A Correct.
Q Now, when you conducted your Medline computer-assisted search to identify all of the studies, did you somehow miss the Fontham study?
A No. It's hard to miss. I had read it before I even started.
Q Before you had even begun working on this

case?
A Yes, it was one of the ones that I -- yes.
Q Now, when you conducted your analysis, when you applied the statistical principles to the residential studies of environmental tobacco smoke and reached certain conclusions, did you consider the Fontham study?
A Yes, I did. Certainly.
Q And when you conducted your meta-analysis of U.S. workplace studies, did you include the Fontham study?
A Yes, I did.
Q Mr. Patrick also asked you yesterday some questions about the size of the Fontham study and the percentage of total cases that was obtained in the Fontham study relative to the other studies; do you recall that?
A Yes, I did.
Q Now, did you go back last night and review all the studies to determine whether or not the Fontham study actually does represent half of the cases?
A Yes, I did.
Q And what did you find in that regard?

A Well, from a back of the envelope type of calculation, it looks as if it represents about 26 or 27 percent of all the cases of lung cancer.
Q Now, I take it there are also -- there are other large studies also?
A In spousal studies.
Q In spousal?
A Yes.
Q There are other large studies, aren't there?
A Yes, there are.
Q Now, when you conducted your meta-analysis in which you found no evidence of an increased risk for workplace exposures, did the Fontham study -- was the Fontham study accorded the most weight in your analysis or was some other study accorded the most weight?
A The Fontham study was accorded the second highest weight. The Bronson study, the second Bronson study, was recorded the highest weight.
Q Why was the Bronson study accorded the highest weight?
A Well, the method of meta-analysis uses

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weights, essentially, inversely proportional to the estimated standard error of their estimate. The standard error is a measure of how reliable their estimate is. And in spite of the Bronson estimate having -- being based on three or four hundred cases, I forgot the number, as opposed to 650 in the Fontham study, it did not have -- the Fontham study did not have the lowest standard error. The Bronson study did. I can go into a long speculation on why, but -- I won't, but --

Q Thank you.

A Okay.

Q So I take it, Doctor, using standard statistical principles involving conducting meta-analysis and determining what weight to accord studies, the Bronson study was more important for analyzing the question of workplace exposure than the Fontham study?

A Yes, but the Fontham study got its fair share of the weight.

Q The weight that it should have gotten under those principles.

A Yes.

Q Let me hand you a copy of the UIC smoking policy that Mr. Patrick provided to you yesterday. Now, that's a smoking policy at the institution that you work at, isn't it?

A That's correct.

Q Did UIC actually conduct an original study of environmental tobacco smoke and health?

A I would be overwhelmed if they did.

Q Were you a participant in the formulation of that smoking policy?

A No, I wasn't.

Q When was that policy first created, Dr. Levy?

A It says effective 1995, but as -- in answering one of Mr. Patrick's questions, we at the Public Health School, had our own no smoking policy from the start of the school, so we did it independently of what our administrators told us to do anyway.

Q And when was the school started?

A 1972.

Q So that policy was developed when, in fact, there were no epidemiologic studies of environmental tobacco smoke in existence.

A First one was 1981.

Q By the way, what does that policy show about -- say about whether or not environmental tobacco smoke is related to lung cancer risk?

A It doesn't address it.

Q Mr. Patrick also talked to you about the report of -- the 1992 report of the United

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States Environmental Protection Agency. Do you recall that?
A Yes.
Q And I believe you told us that the United States Environmental Protection Agency conducted a meta-analysis using at least the same statistical principles that you used in conducting your meta-analysis. Is that right?
A Yes.
Q Now, did the United States Environmental Protection Agency make any adjustment to its meta-analysis for confounding?
A No. It's very difficult to. They assessed the impact of confounding, but you can't do it in the meta-analysis very easily. The individual studies have to adjust for the confounding.

Q Did the United States Environmental Protection Agency meta-analyze the studies for residential exposure or for workplace exposure like you did?
A They did residential exposures exclusively.
Q In fact, did the United States Environmental Protection Agency analyze the workplace epidemiology studies?
A I don't think it was mentioned at all in their report.
Q How many epidemiology studies were available when you conducted your analysis, Doctor?
A Of the workplace?
Q No. Total. Total epidemiology studies.
A In the U.S., I believe 16 studies.
Q How many were available when the EPA conducted its analysis?
A I believe there were 13.
Q Thirteen. So the EPA considered fewer studies than you did.
A Are we talking U.S. studies?
Q Yes, sir.
A Yes. U.S. They -- there were 13 available, fewer studies than I have looked at, and -- yeah, there were 13 available.

Q There were 13 studies available to the U.S. EPA?
A Yes.
Q They didn't actually consider all 13, did they?
A No, they did not.
Q How many studies did the EPA consider?
A Eleven.
Q Now, had the EPA included in its meta-analysis all 13 studies that were available to it, would that have changed the results of its meta-analysis?
A I believe it would have. Of the EPA's meta-analysis, of the U.S. studies.
Q And how would it have changed the results, Doctor?

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A It would -- if they had used 13 available at the time, at the time of the publication, they would have found a non-significant result.
Q Okay.
A Their confidence intervals would overlap one.
Q Now, as Mr. Patrick pointed out this morning, the standard confidence interval to

assess statistical significance with is the 95 percent confidence interval, isn't it?
A Correct.
Q Now, what confidence interval did the U.S. EPA use?
A They used 90, but they had started with 95 in an earlier draft. And for some reason they changed them from -- they changed their strategy from -- or their statistical strategy from -- they went from 95 percent to 90 percent.
Q So, Dr. Levy, is it your testimony that, based upon your review of all the drafts of the EPA reports, that the EPA changed the confidence interval that it was using to analyze these studies during the course of their review?
A Yes, the initial draft that I saw used 95 percent confidence intervals.
Q Had the U.S. EPA stuck with the 95 percent confidence interval, would it have been able to reach a conclusion that the studies showed statistical significance even restricting its attention to 11 of the 13 studies?

A I believe it would not.
Q This morning Mr. Patrick showed you the Hackshaw article. Do you recall that, Dr. Levy?
A Correct.
Q Now, what was the date on that article?
A It was 1997, October 18th.
Q So at least those investigators and the British Medical Journal thought that the question of environmental tobacco smoke and lung cancer required further analysis in 1997, didn't they, Doctor?
A Yes. At least they published an article for the 1997 issue.
Q And I believe that either you or Mr. Patrick pointed out that Hackshaw and his co-authors actually looked at 37 epidemiology studies; is that correct?
A Correct.
Q How many epidemiology studies did you find when you conducted your analysis?
A Well, for my --
Q Total.
A Total available, all countries, 46 at the time.

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Q So you found nine more studies than Hackshaw actually looked at?
A Yes.
Q Mr. Patrick talked about there being a meta-analysis contained in the Hackshaw article. Do you recall that?
A Yes.
Q And what is that a meta-analysis of, Doctor?
A It's a meta-analysis, I believe, of household studies.
Q Does the Hackshaw article contain a meta-analysis of workplace studies like you did?
A In the two or three minutes I looked at it, I didn't see one.
Q Go ahead, take a look at it for us, please.
A No.
Q Actually, Mr. Patrick asked you about a series of conclusions reached by others and documents produced by others. Did any of the documents or reports that Mr. Patrick showed you contain a meta-analysis of workplace studies like you did?
A Workplace, no. I don't think I've seen a meta-analysis of workplace studies.

Q One more question on that Hackshaw article. Mr. Patrick had you read the key messages contained in that article. Can you turn back to that panel? I think it was a panel close to the end of the report.
A Okay.
Q What key message did Hackshaw and his co-authors reach with respect to the risk of lung cancer from workplace exposure to environmental tobacco smoke?
A The six bullets that they have there do not indicate anything about workplace.
Q Okay. Mr. Patrick asked you some questions about whether or not the workplace studies that you reviewed may have, in effect -- may have, in fact, contained persons who had less environmental tobacco smoke exposure than Mrs. Wiley. Do you recall that?
A I don't remember his mentioning Mrs. Wiley, but he dealt with that kind of issue, yes.
Q I think you told him that the studies themselves don't provide the type of information necessary to evaluate what precisely the subjects' exposures were; correct?

A Correct.
Q So some of the subjects in these studies may have, in fact, had far higher exposures than Mrs. Wiley?
A I suppose that's possible, yes.
Q We simply don't know from the studies, do we?

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A We don't know from the studies what their -- the actual individual exposures were.
Q Dr. Levy, is the question of whether environmental tobacco smoke exposure is associated with an increased risk of lung cancer currently being researched by public health authorities?
A I believe it is.
Q And who is currently researching this question, Dr. Levy?
A I know there is a study that has been done by the International Agency for Research on Cancer which is a WA -- World Health Organization agency, affiliated in some way. And --
MR. PATRICK: Your Honor, may we approach on this matter, please?
(Bench discussion)

THE COURT: Go ahead, Mr. Furr.
Q Dr. Levy, is the International Agency for Research on Cancer part of the World Health Organization?
A Affiliated in some way, yes.
Q So at least the International Agency for Research on Cancer and the World Health Organization believe that this question is worthy of further research.
A To the point where they conducted a study in the late '90s and published an abstract in one of their reports very recently on the findings which --
Q Don't tell us about those findings, please.
A Okay. I wasn't going to. I was just --
Q Just a few more.
Dr. Levy, yesterday Mr. Patrick asked you some questions about whether there have been studies conducted of environmental tobacco smoke exposures in the hospital and whether those exposures produce any risk among nurses working in those hospitals. Do you recall that?
A Yes.
Q Are there any such studies in existence to

rely upon, Doctor?
A To my knowledge, no. I haven't been able to find any.
Q Dr. Levy, did any of the questions that Mr. Patrick asked you yesterday and today change in any way any of the opinions that you expressed to this jury yesterday?
A No, they didn't.
MR. FURR: Dr. Levy, thank you for your time, and be careful driving back today.
THE WITNESS: Thank you.
THE COURT: Mr. Patrick, anything else?
MR. PATRICK: Two questions.
RECROSS-EXAMINATION

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BY MR. PATRICK:
Q Dr. Levy, the Fontham study in 1994, that was an original large American study, and they concluded that ETS was a cause of lung cancer; correct?
A Yes.
Q And then in 1996, they went back and analyzed some of their data on workplace ETS exposures and concluded that workplace ETS

exposures cause lung cancer; correct?
A I don't remember -- I know what you're talking about. There was a letter to the editor by someone named Reynolds.
Q Reynolds?
A Who was on that team, and actually -- and they presented a corrected estimate of workplace exposure, which is the one I used in my meta-analysis.
Q And their --
A I used their higher estimate.
Q And their corrected estimate actually showed that the risk of lung cancer from ETS in the workplace was higher than they originally estimated in 1994.
A Their second estimate, their corrected estimate, was higher than the one they originally had, which seemed to be much higher than any of the ones found in any of the other workplace studies.
Q And this was in -- they did their corrected estimate in 1996.
A They corrected -- they did their statistical -- their corrected statistical manipulation came out in 1996, evidently, as

a reaction to something; and because there was another letter to the editor in that same journal, and -- but it's based on the same data. There was no new data in it.
Q Right.
A Okay.
MR. PATRICK: Thank you, Dr. Levy.
THE WITNESS: Thank you, sir.
THE COURT: Doctor, that's all. You may step down. Have a safe trip back.
THE WITNESS: Okay. Thank you, Your Honor.
THE COURT: Call your next, Mr. Ohlemeyer.
MR. OHLEMEYER: Your Honor, we call Christopher Coggins.
THE COURT: Raise your right hand.
DEFENDANTS' WITNESS, CHRISTOPHER COGGINS, SWORN
THE COURT: Be seated, please.
THE WITNESS: Thank you.
THE COURT: Would you tell this jury your name.
THE WITNESS: My name is Christopher Richard Emerson Coggins.
THE COURT: Would you spell your

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last, sir.
THE WITNESS: C-O-G-G-I-N-S.
THE COURT: Thank you.
DIRECT EXAMINATION
BY MR. OHLEMEYER:
Q Dr. Coggins, am I correct you're a toxicologist?
A That's right, sir.
Q Tell us where you live.
A I live in [DELETED] in a place called [DELETED] in a city called [DELETED].
Q We've had a witness from [DELETED], we've had a lawyer from [DELETED] and they don't have the accent you have. Where are you from originally?
A I'm from England originally.
Q And how long have you been in [DELETED]?
A Approximately 12 and a half years.
Q What do you do there?
A I work for the Lorillard Tobacco Company, which is based in Greensboro, North Carolina.
Q Do you have a title?
A Yes, sir. I'm the senior vice president of

science and technology.
Q And how long have you been at Lorillard?
A I've been with Lorillard approximately 15 months.
Q So approximately when did you start?
A That would be January 1 -- sorry, December 1, 1996.
Q Where did you work before you were at Lorillard?
A Before I worked with Lorillard, I was with RJ Reynolds Tobacco Company.
Q And how long were you at Reynolds?
A Approximately 11 years, something like that.
Q So about '85? '84?
A August '85, that's right.
Q And then what did you do before you were at Reynolds?
A Before I was at Reynolds, I was at a contract research lab in Geneva, Switzerland, called Battelle.
Q And how long were you there?
A About nine and a half years.
Q So --
A That would be, I guess, '76.
Q And before that in school?

A Before that in school.
Q Tell us -- and Lorillard is a defendant in this case, to your knowledge?
A I believe that's true, yes.
Q As is Reynolds.
Tell us what Battelle is. We've heard a little bit about Reynolds and Lorillard.

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Tell us about Battelle.
A Battelle is a contract research laboratory. They're based in Columbus, Ohio. They were set up in the will of a gentleman called Gordon Battelle to form a research institute that was halfway between the university and industry. Their biggest invention was the xerography process.
Q Xerography?
A Photocopying.
Q Xerox?
A Yes.
Q And what sort of things does Battelle do, did they do while you were there?
A Well, the four different labs that form the Battelle Memorial Institute do different things. The lab I was based in in Switzerland did largely industrial work for

a number of industrial sponsors throughout Europe. The labs in the U.S. did also some industrial work, but much more government, federal government work.
Q Did you have a specialty or an area of interest at Battelle?
A Yes, I worked for a tobacco sponsor that was there for many years, I worked with them.
Q What kind of work did you do?
A I did inhalation toxicology. I started off from the ground up with groups of technicians coming from my schooling. I learned toxicology from the way a technician would do it, and obtained my skills literally on the floor.
Q And we'll talk about this in a minute. Tell me generally what you did at Reynolds.
A My work at Reynolds was divided into two parts. The first part, when I arrived, was to work, again, in inhalation toxicology, on development of a novel cigarette called Premier. And so that took me probably through the first seven years that I was there.
The second part of my time there I was

moved into a group called smoking and health, where my primary was to understand a much broader set of published work on cigarette smoke in general.
Q And then describe for us, Dr. Coggins, what you do at Lorillard.
A In the short time that I've been there, I really have three remits. One is to maintain the smoking and health.
Q Can I interrupt you for a moment?
A Certainly.
Q You used the word remits. What do you mean by that? Words are different over here.
A I see. I have three basic jobs within Lorillard. The first is to continue my understanding of the smoking and health

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literature, the second is to establish medium and long-term goals for our research and development department, and the third main area is to sit on technical committees, external groups, that Lorillard is a member of.

Q What do you mean by literature?

A Read papers that come out as they relate to our products and cigarettes in general,

understand those, interpret those, and in some cases forward information to my boss.

Q And what are technical committees? Describe that for us.

A Lorillard is a member of a number of technical committees where the industry has pooled resources. A good example would be a group called the Center for Indoor Air Research, where Lorillard is a founding member of a group that will evaluate indoor air problems along with other members of the tobacco industry.

Q And research and development refers to what?

A We have an R & D group also based in Greensboro. I'm trying to find out what it is they do. I haven't had a great deal of success in the short time that I've been there. That's my main task, I think, from now on.

Q Research in what areas and development in what areas?

A That's what I'm not quite sure about. We have a research group that is, in longer term interests, such as, for example, one of the areas I know they're working in is

storage problems of our product, with tobacco, the problems of long-term storage of material in warehouses.

The development side, I know much less about, and this is in terms of developing new products. I don't know much about what they do just yet.

Q In general, is your background and your experience on the research side of things as opposed to the development side of things?

A Yes, that's very true.

Q Tell us, Dr. Coggins, about your college education.

A I obtained a bachelor's degree from the University of Glasgow, in Scotland, and as part of that I did a short research program which would be kind of equivalent to a master's degree here. I then moved to the University of Edinburgh, also in Scotland, where I did a Ph.D. at the Animal Diseases Research Association. So I wasn't actually in school; it was a research institute that I worked in.

Q Do you -- is the area of your Ph.D. in toxicology?

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A No, it's actually in agriculture. I worked at the lab where they produced the sheep, Dolly. That was where I worked.
Q And then have you become certified in general toxicology?
A Yes. As soon as I joined RJ Reynolds in '85, I took my certification, my boards examination, which is the American Board of Toxicology, and I obtained that certification in 1985, I believe.
Q Tell us what toxicology is.
A There are a number of older definitions. I think the definition I would use today would be the study of foreign materials on the body, the study of the effects of foreign materials on the body.
Q And how are those effects studied by toxicologists?
A The basic context that you would use is that you expose animals to test material, or in some cases even humans, and study the effects and try and establish what dose you can administer without producing an effect. And this would be called the no adverse effect level.

So the dose makes the poison; how much dose you need to administer before you can administer different kinds of responses.
Q Are there substances to which exposure occurs at some levels with no adverse effects where at other levels there are adverse effects?
A Yes. The dose is the main determinant. There are some -- there are no materials that are without danger. It's a question of how much of that material you use.
Q Doctor, do you belong to any professional societies in your field?
A Yes, I do.
Q Can you tell us about those. First of all, tell us what professional societies are and why you participate in those kind of activities.
A There are probably two basic types of professional societies, one which is just a loose grouping of people who have common interests and they tend to produce a journal. A good example here would be the American Association for the Advancement of Science. You pay your money, they send you

the journal, and that's -- that's pretty well it.
The second group is really of a professional society that requests certain kinds of abilities before you can become a member, and these can be quite prestigious. For example, I'm a member of the Society of

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Toxicology. And to be even considered as a member for that group, you have to be active in the field, you have to have published in the field for at least three years before they will even consider you to be a member.

Q Are you also a member of the American Board of Toxicology?

A Yes. The board certification exam I just mentioned is rather different from the other societies. You sit the exam to be admitted into the society. You're then called a diplomate of the society. The society says you must retake that exam every five years; actually you take half of the exam. So every five years you have to resit the exam to prove that you are still certifiable as a board certified toxicologist.

Q And are you also a member of the Society of

Toxicologic Pathologists?

A Yes, I'm an associate member of that group. This is sort of a halfway membership. I'm not a pathologist. A lot of my work has involved rodent, rat pathology, and I applied to join the society and was accepted into the membership last year.

Q And how is it that your work involves rodent pathology?

A Virtually all of my work in inhalation toxicology, as we've just described, has involved exposure of rats to cigarette smoke and examination of those responses in the rats. This usually means putting the animals to sleep, taking the organs, slicing the organs up, and looking at the organs down a microscope to see what kind of changes have been produced.

Q And in terms of inhalation toxicology, is that a -- are animal experiments part of inhalation toxicology?

A Yes. Within toxicology you have basically three main ways of materials getting into the body. One would be through the skin, which we call dermal; one would be through

oral, by the food or water; and the third is, of course, inhalation, the material you would breathe in and out.

Q Have you published papers in your field?

A Yes, I've produced -- published a number of papers in this field.

Q Can you describe generally what types of papers and what type of journals they have been published in.

A The bulk of my work has described changes in rats, some papers in mice, exposed to cigarette smoke by the inhalation route for different periods of time, and it described the kinds of changes that were seen in those animals over the different exposure concentrations and over the different

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exposure durations.
Q And can you give me some sense of how many of those types of papers you've published?
A Oh, 40, 50. I haven't counted them up.
Q And when we say "published," explain the process of publishing a paper like that.
A The papers that I've published are all in the peer-reviewed literature. What this means is that I generate a manuscript,

usually along with my colleagues, and I submit that to a specific journal; say, Fundamental and Applied Toxicology is a journal. Inhalation Toxicology is another journal.

The editor of that journal will receive the manuscript and say, I know people in this area with expertise who will review it for quality and for believability. He will usually send this manuscript to two, three, sometimes up to five reviewers. Those reviewers will critically examine the paper and send anonymous comments back to the editor who then forwards them to the scientist.

Occasionally the editor will say the paper is acceptable as it is, but usually the reviewers will indicate changes that they think are necessary. So it is a true review of your work by your peers.
Q And have you served as a reviewer for journals?
A Yes, I routinely review journals -- routinely review manuscripts for probably four or five journals today.

Q Which journals are those?
A I review for the journal Inhalation Toxicology, and I'm on the editorial board for that. I review for Toxicology. I have reviewed for Fundamental and Applied Toxicology. I have also reviewed for the American -- I always get this one wrong -- Industrial -- American Review of Industrial Hygiene. I haven't quite got that right. And there are a few others that I cannot think of.
Q Have you ever served as a reviewer for articles that have been published in the British Medical Journal?
A No, I have not.
Q What about -- tell us what it means to be on the editorial board of these journals.
A The editorial board tries to set direction for the journal. Where does the journal want to go? Does it want to grow, does it want to go electronic? For example, a lot of journals these days are now going electronically available. So we try and set policy for where the journal itself wants to go as a learned treatise.

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Q Dr. Coggins, have you presented what are known as posters at meetings of your professional societies?
A Yes, I have.
Q Tell us what a poster is.
A I poster is something fairly new that is used in, for example, the Society of Toxicology. And the poster is a way that you try and get closer contact between the author and my colleagues, my peers. So instead of either standing up on a platform and making presentation and receiving questions, which isn't very personal, or publishing in a journal and receiving comments as letters, which is also very impersonal, the Society of Toxicology has a policy for writing your paper in the same way that you would as a manuscript for publication.

But you pin it up on a board, approximately the size -- maybe a little larger than this one here, and these are pinned up in a large hall. You stand beside it for a couple of hours, and then your peers walk by. And they stop and say, I

don't think that's right, or you've made a mistake here, or this needs review. So it is a different kind of -- way of presenting your data to your peers.

I believe it's also really peer review.
Q Who attends those types of meetings?
A I just came from the Society of Toxicology meeting last week in Seattle, and there were almost 5,000 toxicologists there.
Q From the United States?
A From throughout the world.
Q Have you given lectures in toxicology at medical schools or other universities?
A I'm an occasional lecturer at the Bowman Gray School of Medicine in Winston-Salem on inhalation toxicology. I've also done the occasional lecture at Blacksburg University in Virginia. One of the more interesting ones is I lecture to a local school of sixth grade children. I have done that for six years, which is very awarding, on the principles of toxicology.
Q And with respect to the posters, I'm sorry, what types of topics have you presented posters on?

A The posters have been very largely the same subjects as we mentioned, of the animal experimentation with cigarette smoke.
Q Are you currently working on any posters or papers?
A I'm not currently working on any posters. I have a couple of papers that are in variety

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of stages of completion.
Q And what subject matters do they involve?
A Again, animal experimentation, but what I'm trying to do is a review of other people's work. So the work that I've done for the moment has described my findings and my results, and my interpretation of those results.
What I'm writing at the moments are a couple of papers where I'm reviewing other people's work to try and pull all of those together to form my interpretation of other people's -- a number of other people's work.
Q We've heard a little bit about this already. When you do your work, publish results of your data, is that known as original research?
A Yes.

Q And then when you go and collect the work of other researchers and review it and form opinions about it, is that known as a review paper?
A That's right.
Q And you're currently working on a review paper.
A A couple, yes.
Q Dr. Coggins, in simple terms, tell us why animal experiments are conducted. What is it that they're designed to do?
A Well, animal experiments are constructed to try to find out, as I said earlier, the now observed adverse effect level for novel materials so that you could make an informed decision as to the likelihood of those materials producing responses in humans.
There are problems with that because rats clearly are not human beings. They can only give you indications of possible changes in human beings. So they are part of a larger battery of tests that are required before extrapolation to human beings can be made.
Q What do you mean by extrapolation to human

beings?
A What does the rat response mean in terms of a human? Clearly the rat is different; it's smaller, it lives a lot shorter period of time. You can't necessarily make a direct extrapolation.
However, there are groups, such as the National Toxicology Program, who say that chronic inhalation studies -- chronic toxicology studies in animals, in their opinion, have a good predictability for human disease.
Q What do you mean by a chronic toxicology study?
A A chronic study would be for something approximating to the life of the animal.

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For rats, that might be two years; mice, a little less time, perhaps 18 months.

Q When you do one of these experiments, how do you decide what type of animal to use?

A This, again, comes back to whether you're working with skin or with oral or with inhalation. The National Toxicology Program routinely says this strain of rat and this strain of mouse is their recommendation.

But for different kinds of studies, for example, for inhalation, there's a very large database of previous studies with rats. So clearly if you know a lot about what has happened in this particular species, the rat, this is a very good reason for continuing.

For oral absorption, the rat tends to be the useful model, too. It comes down a lot of the time to practicality. If you want to look at the responses in a statistical way, you need large numbers of animals. It's very difficult to use large numbers of, let's say, dogs or primates, which have been used in the past, but are very unpopular today.

Q When you talk about toxicology and animal experiments, do you have to use animals? Are there any other types of toxicology experiments you can do?

A Yes. I'm not an expert in these areas, but there are things called in vitro, or literally in glass techniques, that can use bacteria, that can use a variety of different techniques. These generally are a

little further away from the human being because they're not in the living organism. But I'm not expert in those areas.

Q How do you decide what type of experiment to use; a skin experiment, oral experiment, or inhalation experiment?

A Well, clearly for cigarette smoke the obvious route is to do inhalation. So I really didn't have much of a problem there.

Q Let me interrupt you, though. There's been some evidence in this case about skin, what are called skin painting experiments, involving cigarette smoke condensate in animals. Are you familiar with that technique?

A Yes, I've done some skin painting studies. These studies I'm not particularly keen on. They are not using cigarette smoke.

Q What do they use?

A They use an apparatus called a tar generator, where you take cigarette smoke which is a combination of particles and gases mixed together, which is called an aerosol, and they condense this using either a cold trap or different types of trapping

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mechanism, and they clearly remove the gas phase. It's gone, because they condense this.

And also, I think other changes go on as you go from the particles in the aerosol to the particles in the solution.

Q What kind of changes?

A I think there are chemical processes that go on as these materials react together.

Q And then what happens in those experiments?

A Routinely what happens in the skin painting study, you take this tar, which is black and viscous; it really is like tar, and you paint this on the backs of mice for periods of up to about two years, about as long as a mouse would live.

Q And how does -- how do you determine how much of that substance to paint on the back of the mouse?

A That is a subject of a lot of controversy. There's real no standard method.

Q And how does the amount of that material that's painted on the back of the mouse relate to the number of cigarettes somebody might smoke or --

A I don't think it does in any way.

Q Do people still use skin painting experiments today?

A I haven't used any for 15 years.

Q Are they used to study other substances?

A Yes. For example, I know they're used to study agents that are protecting against suntan. Suntan lotions, that kind of thing.

Q Sunscreen?

A Sunscreen, that's the word.

Q How do you -- when are oral experiments used?

A Oral experiments would be used for materials that you might be ingesting. For example, new -- new antibiotics; for example, new drugs. Other materials could be sometimes administered in water if that might be the route of administration that the human would be exposed to.

Q And then are inhalation experiments used for other substances besides cigarette smoke?

A Absolutely. The lab I worked in in Geneva, I was on the second floor, and the first floor was doing a very large study of the inhalation of diesel exhaust.

Q And how is it -- what is it -- when you do an experiment like this, what is it you're looking for at the end of the experiment?

A Well, it very much depends on the design of the experiment going in. Some experiments are simply looking for what kind of change you can produce with technique A as opposed

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to technique B. Other studies are looking for longer term responses which might be -- include cancer. It depends very much on your design of the experiment going in.

Q And how long do these experiments typically last?

A As I say, up to the length of the life of the animal, although that isn't a standard. I would say today probably the rat, a chronic study, a long-term study, would be about 24 months.

Q With respect to inhalation experiments involving cigarette smoke, what type of rats are used? Where do you get the rats?

A The important factor here is to buy animals that are disease free. That if you buy animals that have got, for example, respiratory tract infection, you cannot

determine whether the results that you find at the end are due to your work or the fact that they were infected with the disease. So it's absolutely paramount that the animals are clean, and there are numbers of animal suppliers that provide different strains of white rats that are disease free.

Q How do you know whether the animal you're using is even capable of producing the type of response you're looking for? Does that make sense?

A Yes, it does. Because what you do then is go back to the database. As I've just described to you, there are a very large number of inhalation studies that have been performed with materials such as diesel and all kinds of other materials. You can go back and look at that database and say, uh-hum, here is a response, this rat, or this bunch of rats didn't get such and such an end point. We know therefore that they can get that such and such an end point.

Q So, for example, with respect to cancer, through inhalation, when you do animal experiments, do you -- how do you know

you're using rats that have the ability to develop cancer?

A Well, for example, the diesel study that I was talking about, those rats did get lung cancer at very, very high concentrations of smoke. There are other materials, go back and look at the database, there are other materials that rats, when exposed to, will indeed get lung cancer.

Q How is it you know that the rats actually inhaled the substance that you're exposing them to?

A That is a technical question that's difficult to answer. And clearly when you're administering material by, let's say by the oral route, it's very simple. You

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can administer it and, say, ah, we've injected such and such an amount. In the inhalation study, it's the animal that decides how much they want to take in. So you don't necessarily know how much they're taking in, unless you do a variety of fairly sophisticated tests. Say here's the quantity that I presented to the animal in terms of milligrams per cubic meter or

whatever unit you want to use. And then clearly you know how many minutes of exposure you have per day, that's fairly straightforward.

But then you have two other variables that routinely are not always measured in inhalation studies that I think you do need. One is the size of the aerosol, the physical size. Clearly, if you expose rats to an aerosol of tennis balls, they wouldn't inhale them, so you have to have particles that are small enough.

And the final variable that I spent some of my time measuring is how much do the animals breathe. What is the amount breathed per minute. And that is affected by the breathing frequency, how many breaths they take, and also the depth of the breath, which is called the tidal volume. These vary enormously in inhalation studies, and I believe you have to take this into account before you can actually assess the amount of material that has been inhaled by the animals.

Q So, and we'll talk about this now in a little bit more detail, but am I correct you've been involved in inhalation experiments involving rats and cigarette smoke?

A Yes.

Q And as part of those experiments, you have determined that those rats have the ability to develop cancer and other diseases?

A Yes. Yes.

Q And that they actually do inhale the smoke you're exposing them to?

A That's true.

Q Doctor, tell us about the work you did at Battelle in terms of animal experiments involving cigarette smoke.

A When I arrived there in '76, there was a study ongoing where a British tobacco company was looking at a tobacco substitute. This was called citrol (phonetic), it was rather like cellulose.

Q Can I stop you there, what's cellulose?

A Wood pulp, simple wood pulp. And it was this experiment that I really learned the various processes of inhalation toxicology, of necropsy, of some of the subsequent

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pathology.
Q Let me ask you again what necropsy is?
A I'm sorry, I use all these jargon terms. Necropsy is where you put the animal to sleep and dissect out the organs and see if you see any changes.
Q Like an autopsy?
A An autopsy. So this was the first study that was ongoing when I arrived there. And the work that I did for the next four or five years looked at the kinds of changes we saw in relatively short-term studies, 90 days, 3-month kind of studies.
We also looked at some of the changes that you would examine -- some of the changes you would see if you only exposed the animals to the particulate phase as opposed to the whole aerosol, as we just described it, and we published that.
And then, as I say, we made a number of evaluations of the way the breathing patterns of the animal, the tidal volume and the breathing frequency, were affected by the cigarette smoke itself.
Q Did you study in any way any defense

mechanisms or physical response of the animals to smoke?
A Yes. These are part of the end points that are routinely built into these inhalation studies.
Q I apologize. Let me interrupt you one more time. What do you mean by end point?
A Okay. The end points are usually the changes that are seen by the pathologist as he looks down the microscope. These would be changes that are seen in the tissues throughout the respiratory tract. And there are a number of different changes that are seen.
End points can also include some of the physiology, which I was describing to you earlier, the breathing frequency and other breathing changes. But I would say the main end point would be what the pathologist sees. But even things like whether the animals continue to gain weight can be an end point. There are large numbers of them.
Q So I interrupted you. You were telling us about some of the end points.
A Yes. One of the things that the pathologist

sees when he looks down the microscope are some changes throughout the respiratory tree as a result of cigarette smoke exposure. And one of these that I think is a defense mechanism is the increased numbers of what are called macrophages, right down in the deep lung. So you go from the nose, voice

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box, windpipe, bronchial tubes, and then right down in the deep lung, which is called the alveolar space, where the gas exchange takes place. It's rather like a sponge. It's very complicated.

Within those areas, these pathologists have seen individual cells, rather like a Pac Man, that are going around engulfing material that's floating in the lungs, and they grab that and kind of digest it. And this was seen in a much more pronounced way in animals exposed to smoke. And I think that's a good example of a defense mechanism.

Q Is it also some evidence that the animals are actually inhaling the smoke?

A Yes, it is.

Q What about -- describe for us the results of

the experiments that were conducted at Battelle.

A The main changes that were seen throughout the respiratory tract were in the lining of the tubes. So we have these free Pac Men floating around in the lung. The other changes were the lining, which really is, if you consider a tube with the smoke passing through it, it's the lining, the part on the inside, which looks rather like skin.

And the kind of changes that we saw were really three kinds: The first kind would be, it's called hypertrophy, which instead of just being a layer of small cells on the inside of the tube, you'd have some of the cells getting a little larger, just physically, a slightly larger cell. And that's a fairly benign change.

The next change that we saw, and again other people have reported this, is a hyperplasia. Hyperplasia means an increase in cell numbers. And that's very simply like a callous that forms on your hand when you do a lot of manual work. You get thickening of your skin. So we saw this in

the nose, certainly very much in the voice box, and to a certain extent in the bronchial tubes, we saw this slight thickening.

The third change is a metaplasia, which is a change in cell type. So we're going from, let's say, a columnar type of cell to a goblet cell. Goblet cells simply are called goblet cells because they look like goblets that are full of mucus, which is another defense mechanism.

So we saw hypertrophy, we saw hyperplasia and we saw metaplasia as we looked throughout the respiratory tract, and those were the only changes, in addition to the macrophage change that I just described,

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those are the main changes that we saw and published.
Q Did INS-DIRECT

smoke.
Q And once the animals were autopsied in this experiment, what observations were made? What were the results?
A What were the results?
Q The results.
A The results were very simple, in that the low dose groups didn't show anything at all in any organ at all. Nothing. They were the same as the controls. So the three to four times higher real world was the same as zero.

The 30 to 40 times group showed nothing at all. They were exactly the same as the control group.

The 300 to 400 group, and I'm talking here of the 65 days, the end of 65, didn't show anything in the lungs, didn't show anything in the bronchial tubes, didn't show anything in the windpipe, didn't show anything in the larynx. They showed a small change in the nose. Now, the rat nose is quite long. And at the back of the rat nose, we didn't see anything; middle of the rat nose, didn't see anything. But right at

the very tip of the rat nose, right at the very front, we saw a small change in the high exposure group at the end of 65 days.
Q What sort of change was that?
A This was a change that the pathologist determined was an epithelial hyperplasia, which was a slight increase in the number of cells lining one small part of the turbinate, which is an organ that hangs down in the air. So it's the callous I described very early on this morning.
Q Is it a cancer or a tumor?
A It is not a cancer and it is not a tumor.
Q Was it a change that was considered to be permanent or reversible?
A We showed clearly that it was reversible.
Q How did you show that?
A We did the reversibility study that I just described to you, and this was for 90 days of exposure, we kept a subgroup of animals for an extra 90 days, and they were back to normal. So within 90 days reversibility, the change had gone away.
Q What other, I guess, end points or observations were made with respect to these

experiments?
A I think the other toxicologically interesting one to me was the fact that this change was not progressive, so we killed animals after 4 days, after 14 days, after

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28 days and after 90 days. And the results were all the same. So the change was there after four days but did not get any worse to 14, to 28, to 90. It was there as a kind of adaptive response. It didn't get any worse. It was just purely an adaptive change.

Q What do you mean by adaptive change?

A Just rather like the callous on the laborer's hands; it comes, it doesn't do anything, and it goes away.

Q And what's the significance of the fact that the changes didn't get any worse?

A That we're not really sure. I think it just indicates that it's a simple response due to repeated irritation, that it does not get any worse. You form kind of a protective layer around this very sensitive tissue in the tip of the nose. Once that defensive layer has been formed, it doesn't get any worse, and it just stays the same.

Q Did you do any work with the cells or any other kind of analysis of individual cells as opposed to the organs of the body?

A Yes. We added on to this study a very sophisticated end point called cell proliferation. And this -- this is fairly complicated and fairly new.

And the idea here is that if tissues are dividing rapidly, and are multiplying, they may be indicating a precancerous change. Because as cells divide quickly, errors are made in the way they divide, and those errors could result in cancer.

So we wanted to know whether or not anywhere in the respiratory tract of these animals there was a higher than normal rate of cell proliferation, just simply the rate of cell division.

So we pretreated these animals with a special technique that basically shows that when you look down the microscope, if a cell is proliferating very rapidly, it's red. It's just like the little thing you have on the turkey when it says it's done, it popped up red. Same thing here with these animals.

So we treated animals in the four groups I just described to you and looked throughout the respiratory tract of those four groups of animals to see if anything was proliferating or whether the cells were turning over quicker than normal.

And very simply, the results were just as I described for the previous set of results, nothing in the low group, nothing in the mid-group, nothing in the lungs, bronchi, voice box of the high group. But only the very tip of the nose in the high group after 90 days there was a small increase in this cell proliferation.

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Q Now, there's been testimony in this case that pathologists can look at the same piece of tissue and come to different conclusions about it. How do we know that someone else might not look at these samples and come to a different conclusion than you have?
A It's true that there's a lot of variability between pathologists. We approached this problem in two different ways. One was to have three separate pathologists look at these tissues. One was the study

pathologist, who is a contract employee; the second was an RJ Reynolds employee, who is also a board-certified pathologist; and the third one was a consultant, who was also board certified, and those three people looked at the slides separately, independently, and came to very much the same set of conclusions.
Q And then were the results of this study published?
A Yes, sir.
Q And what was done with the pathology slides from this study?
A What's routine in studies like this is to keep the various tissues, which would be the organs as they've been harvested, the blocks that they have been used to take slices from, and indeed the glass sides. Normally, they're kept in an archive in the laboratory that performed the work, ourselves.
We decided, because of the interest in the subject, that we would donate the entire study, everything, from protocol right through to the very last animal, to an organization that would allow other

scientists, other interested scientists to go and look. And we hunted around for a firm that would do this, and found the largest group, which is called the Armed Forces Institute of Pathology. They're based in D.C., and they're a large repository of human and animal tissues. And basically, if you've got the correct qualifications, you can go in there and say, "I want to see the Reynolds study on ETS," and they'll let you in to see it.
Q Doctor, based upon this experiment with aged, diluted sidestream smoke -- let me ask you this: Have other investigators done experiments since then involving either aged, diluted sidestream smoke or environmental tobacco smoke?
A I'm not aware of anybody using environmental tobacco smoke, because of the difficulty in including the human exhaled mainstream. But there are several groups that have done similar studies to ours, yes.
Q And how do the results of those published

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studies compare to the results of the Reynolds' study?

A I think in general very similar results have been found restricting the responses to hyperplasia of the upper airways.

Q Are you familiar with research done by an investigator named Witschi, W-I-T-S-C-H-I?

A Yes, I am.

Q And who is Dr. Witschi and what type of work has he done, or she done?

A Hansbury Witschi is a Swiss M.D. working in California, and he has performed a study using an attempt at environmental tobacco smoke using ADSS and some mainstream component. And he has come up with two papers -- actually three papers very recently.

The first paper had a concentration right in the middle of ours. He only used a single concentration. And showed results actually fairly similar to ours using a mouse.

His second study used a concentration almost ten times higher than the concentration we used. He only used a single concentration. And he used a very -- I'd like to use the word peculiar but that's

not right -- an unnormal strain of mouse. It's a strain that is used to study cerebral palsy, where you have the split palate, cleft palate, excuse me, cleft palate. This mouse has been developed to study this with. He used this strain of mouse.

This strain of mouse has a very high incidence of lung tumors, all -- you know, by a year old, virtually all of the animals have lung tumors. So he used this strain of mouse, and he exposed animals to the longest concentration of smoke similar to ours, but ten times higher.

At the end of his five-month study, a little longer than ours, he saw tumors in both groups, the smoke-exposed group and the controls. Same incidence. But interestingly, and I'm a little baffled by this, he kept some of the animals for an extra two months, and at this point he found a change in the incidence of the tumors between the groups. And that was because -- and that showed that the incidence of tumors was higher in the smoke group than in the controls. Even though it wasn't any

different at the end of the experiment. So something changed, something happened in the reversibility period, instead of the changes going down, they went up.

Q And what, if anything -- what conclusions

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can you draw from those experiments and your -- well, let me ask it this way: Based on your animal experiments with aged, diluted sidestream smoke, and based on your review of the literature and the work of others, do you have an opinion based upon reasonable certainty as to whether animal experiments prove that exposure to environmental tobacco smoke or aged, diluted sidestream smoke causes cancer, lung cancer in nonsmokers?

A I do have an opinion. I think --

Q What is that opinion?

A I think the animal studies show that it's very unlikely.

Q And what studies do you base your opinion on?

A I base it on the inhalation study that I performed, specifically with the cell proliferation end point built in, just

showed that even at very high concentrations of ADSS, at six hours a day, at 300 to 400 times real world concentrations, using this very sophisticated assay, the cell proliferation assay, we did not see anything in the lungs of these animals.

Q And is it possible to produce tumors in the lungs of animals?

A Yes. A number of materials have been shown to produce tumors in the lungs of animals such as rats and mice.

Q And efforts to do so with smoke, mainstream or aged, diluted sidestream smoke, have been negative?

A That's correct.

MR. OHLEMEYER: Thank you, Doctor. That's all I have.

THE WITNESS: Thank you.

THE COURT: Mr. Westbrook.

MR. WESTBROOK: Thank you, Your Honor.

CROSS-EXAMINATION

BY MR. WESTBROOK:

Q Hello, Dr. Coggins.

A Hello.

Q How are you?

A Thank you.

Q Dr. Coggins, am I correct that you're a senior vice president at the Lorillard company?

A That's right.

Q Okay. And you mentioned in your direct testimony that the boss, I think you mentioned the boss -- is the boss a Dr. Spears?

A Yes, that's right.

Q All right. And he's the man you report to?

A That's right.

Q He's the man who hired you?

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A I'm not sure if it was he who actually said yes, that he hired me. I was interviewed by a head-hunting agency, and I think -- presumably Dr. Spears and others were involved in the hiring of me from Reynolds just over a year ago.
Q All right, sir. If we can, Doctor, I want to spend a few minutes and discuss a little bit about your work history. I have put up an outline. We'll discuss the dates. It's a little small to read, so I'll mention them

to you as we go along. See if we can capsulize your history with the tobacco industry.
As I understand, I think you repeated part of it on direct, that from late '76 to July '85, you were employed by the Battelle Company laboratory and the funding for your actual work, by and large, came through a British industry tobacco company called Gallaher; correct?
A When you say by and large?
Q 85 percent.
A Something along those lines, yes.
Q Now, although you were with Battelle from '76 to '85, the Gallaher money ran out about 1982 or so?
A I think that's right.
Q Okay. And from 1982 to July 1985, you were still at Battelle, but your actual work, except for some finishing up, had basically ended; correct?
A I was doing some finishing up of studies that had been performed, writing them up, but at that time I was still being paid by Battelle.

Q Sure. And your primary activity for these, this period of time, was to look for more tobacco industry funding so that you could continue some work at Battelle. That's true, isn't it?
A Yeah. I had a large group of technicians and equipment that I wanted to maintain, and I visited other tobacco companies and said, look at these facilities that we can offer to you.
Q And a lot of the other technicians who were with you went off and they worked on other projects within Battelle; is that right?
A Yes, some of them went to the diesel studies, some of them went other ways, yes.
Q But because Gallaher had asked that you be a principal investigator and devote your time solely to their project, when they pulled out, you were basically left with no other project; is that right?
A They indicated that they would not be very keen on me working for other sponsors, other than themselves, but I don't think if I had

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found somebody and said, Look, this will take up 10 percent of my time, I don't think

they would have objected. They wanted me to be sort of the, someone at the other end of the telephone from London that would answer their questions, yes.

Q And in parlance, you had sort of put all your eggs into the Gallaher basket out there at Battelle. That was your project?

A No, I think I put all of my eggs into the Battelle basket.

Q And within Battelle, the Gallaher project was the one you were working on exclusively?

A That's right.

Q All right. And from 1982 to 1985, you were looking for money.

A As I say, I was still employed by the Battelle Company. I was looking for work from other tobacco companies.

Q Funded work?

A Yes.

Q Okay. And you were looking for money from the tobacco industry, that's where you concentrated, because that's where your experience was?

A That's right.

Q Okay. In the course of looking for that

work from the tobacco companies, you contacted every one of the major American tobacco companies, didn't you?

A I believe that's right, yes.

Q All right. And none of them were willing to fund you at Battelle.

A All of them were very interested in my work, knew of my published studies, were very interested to have someone come and visit them, but all of them said at the time they were not interested in pursuing any studies at Battelle, that's right.

Q Thanks, but no thanks?

A I guess, yeah, that would be about right.

Q But as a result of that, you made some contacts in the American tobacco industry, and you eventually got on with Reynolds in August of 1985; correct?

A As part of my grand tour of the U.S. tobacco companies and, indeed, others, I did indeed make contact with the Reynolds people, and I presume that it was that that resulted in them subsequently contacting me and saying we have a job for you, yes.

Q And certainly after two years or so of

looking for something to do, you were happy to get on with Reynolds, weren't you?

A It was a difficult move. I had spent a long time in Geneva, didn't particularly want to leave Geneva, but at the same time, I wasn't

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sure where the Battelle lab was going. The Gallaher work had disappeared, the diesel work was finished, and I was unsure whether or not Battelle would survive.

Q So you were faced with either Geneva and no job, or North Carolina and a job. And you chose the job.

A It was a bit more complicated than that, in that I didn't have a work permit.

Q So you had no work permit to come to this country?

A That's correct.

Q Have you subsequently gotten a work permit?

A Yes, I have.

Q But you're not a citizen of this country?

A No.

Q Now, you got on with Reynolds, and it's clear that from August 1985 to late 1996 when you were working for Reynolds, all your funding, that is your salary, whatever

benefits you got, came from the American tobacco industry through Reynolds.

MR. OHLEMEYER: I object to the question as framed, Your Honor. He was employed at Reynolds. I don't think that funding --

MR. WESTBROOK: I thought that's what I said, Your Honor.

THE COURT: Overruled. Go ahead.

A I was working with RJ Reynolds for those ten years, yes.

Q Okay. And then in late 1996, you moved over to Lorillard primarily because Lorillard offered you a substantial salary increase; correct?

A Primarily, but not only.

Q Okay. And since that time, you've been an employee of the Lorillard company, and you came over as a senior vice president, didn't you?

A I'm not quite sure. The position I was offered was a senior vice president, yes.

Q Okay. All right. So to capsulize, Dr. Coggins, since you got out of the university and began to work in Switzerland,

with the exception of a small percentage at Battelle that may not have been Gallaher, is it true that all of the funding and all the support that you've had has come from the tobacco industry, either here, or over in England?

A I think my answer is clearly that over the last 15 years that the payments, my salary, has clearly been paid in the U.S. by U.S. tobacco industry. I still maintain that my work in Switzerland was funded by Battelle and not by Gallaher.

Q All right, sir. Now, we mentioned Dr. Spears; I believe you admire Dr. Spears,

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don't you?
A Yes, I do.
Q And do you agree with Dr. Spears' view that it's never been proven that Lorillard cigarettes have ever caused lung cancer in any American?
A I don't know whether Dr. Spears ever made such a statement. The whole concept of causation depends very much on the definition used. I don't know what definition he was using. It may not be the

same definition as the one I would use.
MR. WESTBROOK: Your Honor, I have a brief excerpt of what we showed Dr. Spears' testimony. I would like to show it to Dr. Coggins.
MR. OHLEMEYER: Your Honor, I continue to object to asking one witness to comment on the testimony of another witness.
MR. MOTLEY: Your Honor, it's an admission of a party, period.
THE COURT: Well, he's already answered the question, I think, to which this applies; am I right?
MR. WESTBROOK: I think he said that he may have a different definition, and I thought that he might see Dr. Spears' testimony and he may or may not agree.
THE COURT: No. Objection sustained.
BY MR. WESTBROOK:
Q Dr. Coggins, suppose every person in this courtroom you knew smoked three packs of cigarettes a day and had done it for 40 years. Would you tell us that in the medical scientific literature, there's

absolutely no scientific proof that that smoking of cigarettes would cause lung cancer?
A First of all, I'm a scientist. I'm not very good with hypotheticals. You're asking me to assume everybody in this room has smoked three packs a day for their lives?
Q Yes, sir. Would you then feel comfortable in saying there's no scientific proof that smoking causes lung cancer, and wouldn't cause lung cancer in any such person?
A My problem, again, is with the use of the word "cause." How you define it. I accept the fact that cigarette smoking is a well-established risk factor for lung cancer. I am uncertain as to the next step in the causation tree to go to, to use the word, absolute word of "cause." It's a risk factor.
Q But you don't agree that smoking causes lung cancer.
A No, I -- my statement is I don't know whether it, cigarette smoking, causes lung

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cancer or not. As a scientist, I just don't know.

Q Okay. As a scientist who's worked in the tobacco field, for the tobacco industry for about 22 years, you just don't know.
A As a scientist, I don't think that the data converts to a common conclusion, and that, therefore, I cannot make a definitive statement. I don't know.
Q And even though you left Reynolds, Doctor, I think it's your view that you still have a loyalty to Reynolds, you still feel loyal to that company, don't you?
A I have many colleagues still there. I feel a certain loyalty to the company I worked for for ten years, yes.
Q And you certainly feel loyal to your present employer, Lorillard; correct?
A Loyalty, I -- yes, I clearly feel a loyalty to the company that pays me.
Q Dr. Coggins, let me talk with you for a few minutes about scientific publications. You said you've published a number of articles in the literature. And let me ask you about the process of publication of scientific articles in your experience. Let's look at Reynolds. That was your longest experience.

By the way, have you published any articles since you've been at Lorillard?
A Yes.
Q And you've published a number of articles when you were at Reynolds; correct?
A That's right.
Q All right. So let's say that you, Dr. Coggins, want to do a study, animal study back in the Reynolds' days, okay, so you get the idea for a study. So let's start over here. You have an idea and want to do a study.
Am I correct, Doctor, that at Reynolds, when a scientist had an idea and wanted to do a study, that the scientist would have to have that idea and that proposal reviewed by several groups at the company including lawyers in-house? Before you even got started and could do it, the lawyers and others had to look at it, and clear it.
A If I were to follow this through -- I'm not sure what your drawings mean. Are those doors?
Q Well, I tried to draw doors, Doctor, and I'm glad you recognize them as such.

MR. MOTLEY: I believe he's a witness who tried a draw a house, Your Honor.
Q You haven't seen my house yet. So my question is, did lawyers have to look at it

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first along with the other groups?
A There were many groups that reviewed my research proposals before we went on and started the study. There were, indeed, lawyers. I think probably only one lawyer. But they also included groups such as management, veterinary care, animal care, large numbers of people in the company wanted to know what my experiment was before they would allow me to go ahead with it.
Q Sure. All right. So lawyers and others reviewed it. And then if the lawyers and the others passed it, then you got right into the experiment stage, assuming there was money available from the company to do it. Okay? So now we're in the experiment stage.
And when you did your experiment, you'd go along, you'd gather your data, et cetera, and eventually you get to a point where you

thought it was appropriate to write up your study and see if you could make something of it in the published literature many times; correct?
A Yes, but --
Q Sure, give me the but.
A The but is to make sure that my experiment could be published. Once the experiment had been completed, I had to make sure that my design was correct, right up front, so the ultimate approval of the experimental design was by scientists. Because if they said this experimental design isn't any good, then no matter how good, bad, indifferent the results were at the end, I'd never get it published because the design was bad. So it had to be up front that I got the scientists to buy it and say, yeah, you've got the right design here, you've got the right end point there. If they bought in at the beginning, depending on how the work then went, it meant that I had a higher probability of acceptance of the manuscript downsteam. So I had to have their approval upstream.

Q Sure. And even when the scientists bought into it, the lawyers were still involved in this pre-experiment review, wasn't it?
A There was a lawyer that reviewed the particular protocol I have in mind, and that was for, I believe, proprietary reasons and financial reasons, and the experimental design was written by the scientists.
Q And the lawyer also reviewed it for legal reasons. Is that correct?
A I don't know.
Q Okay.
A I'm a scientist.
Q Okay. And then you did your experiment,

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when you got ready to write it up, then you had another level of review and this same group came back into play; didn't they?
A That's correct.
Q Management, scientists, and the lawyers also had to look at your manuscript before that manuscript could be submitted for publication; correct?
A Yes. The process was such that at the end of the experiment, the job of the principal investigator, which in these cases would be

myself, put together a draft, perhaps a couple of drafts, arrive at a working draft that the scientists felt was the way they wanted it to go. That draft then went back to the same protocol review group and said look, or pretty well the same group, this paper we want to submit for publication in the outside world. And basically we had to get the same set of approvals from company representatives from a variety of different places to say yes, you may take this manuscript and submit it to the journal, so yes.
Q Okay. And here when you had your manuscript and were thinking about submitting it to the journal, not only did lawyers from inside Reynolds look at it, but on occasion at least the manuscript had to be sent to outside lawyers to review, such as the Womble Carlyle folks?
A I'm not sure about had. I may have asked for comments. I don't think there's any formal loop within the Reynolds R & D group that said this paper, once it's been approved, has to be reapproved.

My opinion as a scientist for getting my paper published is I want it to be reviewed by as many people as possible so that they can point out whatever flaws there are in it, before it gets to the journal so that they won't reject it. I want to get approval by as many people upstream as possible.
Q And do you recall telling me that the review by lawyers would have included the Womble Carlyle firm?
A I don't recall our conversation exactly, but I don't think that the manuscript had to go to Womble Carlyle.
Q And do you recall telling me that Mr. Furr was sometimes involved in the review process?
A I remember talking to you about Mr. Furr, yes.
Q Now, in addition to this publication procedure, there was also a procedure at Reynolds, was there not, when you wanted to present a public position on behalf of

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Reynolds, such as before a congressional committee, whereby your text would be

reviewed by a number of people to be sure that it was compatible with Reynolds' interests. You recall that, don't you?

A Well, I recall the initial statement, but I think there are a couple of statements in there I would not necessarily agree with.

Q Well, let me ask you this specifically: When you appeared before a Senate subcommittee to give testimony about tobacco smoke issues, did you have your proposed script reviewed by lawyers?

A Yes I did.

Q And did you have that testimony also reviewed by outside counsel such as Mr. Furr?

A I can't remember but I think that's probably true.

Q All right. And when you testified before the Waxman hearings, were there lawyers for Reynolds sitting in the audience listening to your performance?

A Yes, I think there were.

Q Now, Dr. Coggins, you have had, have you not, a number of media training sessions to prepare you to present yourself in public on

behalf of the tobacco industry or tobacco company, haven't you?

A No, that's not quite right. I've had a number of media training classes in general. Not specific to any industry, just how to -- how to get my scientific ideas across to non-scientists.

Q All right. And at those media training classes, Doctor, you would on occasion, at least the first few, you would be taught some things about how to present yourself and then videotaped doing some presentations, then you'd watch the videotape and see how you did; correct?

A We did a number of such sessions, yes.

Q All right. And as the sessions went along, Doctor, you apparently got pretty good at it and you were used within Reynolds as an example for other scientists of how to present yourself on behalf of Reynolds in a public forum; do you remember that?

A I think once or twice that I was used as an example; whether it was good or bad, I was used as an example for other scientists, yes.

Q And were you -- do you recall being used as an example at a class at which Dr. Ogden attended who was here the other day from Reynolds?

A I'm not sure if I remember that at all.

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Q In all, is it true, Doctor, you've been through about ten or so of these media training classes.
A That was the number I remembered giving you. It is a guesstimate, at least something like that.
Q In addition to sometimes presenting a public position or testimony on behalf of Reynolds, have you also appeared and given testimony on behalf of the Tobacco Institute?
A Just a second. You had a phrase there that I disagree with. I did not present tobacco or industry position. I presented my views on the science. I was not given a position by anybody else. I presented my views on the science involved.
On the second part of your question, I'm sorry, I missed.
Q I'll get there now with that clarification. When you were presenting your views on

behalf of the science, the views that had been cleared through that review process, did you sometimes present those views on behalf of the Tobacco Institute?
A I did once present my views to, I believe it was a Senate subcommittee, on behalf of the Tobacco Institute, yes.
Q All right. And on that occasion, before you gave your testimony on behalf of the Tobacco Institute, did you give Tobacco Institute personnel your text, tell them what you were going to say, and get their comments on it?
A That's right, yes.
Q Okay. And the group that was engaged in that review of your proposed testimony also included lawyers, didn't it?
A I'm not sure. There was a group of people there, they had lots of questions, and there may have been lawyers there, I'm not sure.
Q Dr. Coggins, you've told me in the past, I believe, that you acknowledge that the tobacco industry doesn't have the best reputation in the world. You remember that?
A This was -- I remember this, yes.
Q All right. Have you seen, Dr. Coggins, in

your work at Reynolds or in your work at Lorillard, any of the internal tobacco industry documents discussing destroying data? Have you seen any of those?
A I have not. I have, quite the contrary, been very aware, both at Reynolds and at Lorillard, of a very strict manuscript retention policy that says that any manuscript that could in any way be related to ongoing litigation must be kept. And as far as I can recollect, I have always followed those policies.
Q And you would be shocked, Doctor, wouldn't you, if lawyers suggested that data be

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destroyed and made those suggestions to scientists, wouldn't you?
A Let me just get this right. You're saying I would be shocked if --
Q Lawyers for the tobacco industry suggested that some data be destroyed. Scientific data. You'd be shocked about that, wouldn't you?
A I think I would, yes.
Q That would be totally inappropriate, wouldn't it?

A Well, it would seem to me that, once you've created data, it would be very unscientific to attempt to muzzle those data.
Q "We work for smokers." Does that sound familiar, Doctor?
A Yes, it does.
Q That was the motto, and is the motto, of the RJ Reynolds Tobacco Company; correct?
A Certainly was when I was there.
Q Okay. The motto never was, we care about nonsmokers, was it? That was never the motto, was it?
A I don't think so. As far as I can remember, it was "We work for smokers."
Q All right. Now, was there a division called the ETS division at Reynolds when you were there?
A I was there for 11 years, 12 years, something like that, and one of the groups within the research and development department that was close to my group was called the ETS department, yes.
Q And that stands for environmental tobacco smoke?
A That's right.

Q Some people call it secondhand smoke?
And on occasion, Doctor, you would get reports, would you not, from the ETS division of Reynolds updating you on the division's activities; do you recall that?
A The boss that I referred to, reported to at the time had I think six or seven departments reporting to him and he requested weekly highlights from each of the seven departments and each of the copies, each of the other six recipients -- other six groups also got copies of the reports that went to him every week, so yes, I would get copies of the ETS Weekly Highlights.
Q Let me show you an ETS Division Weekly Highlight from September 11, 1990, and ask you, sir, if you recognize that as being on the form that those reports were generated in, at least sometimes.
A It's been almost eight years since I've seen these but this looks -- it certainly has the right names on it, yes.
Q Yes, sir. And you're looking at the logo on

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the side. That means produced by RJ Reynolds Tobacco Company. That's what that

stamp means.

A Okay.

MR. WESTBROOK: Your Honor, we would move September 11, 1990 ETS Division Weekly Highlight Report into evidence as the next exhibit number.

THE COURT: 92. You had a chance to review this, Counsel?

MR. OHLEMEYER: Yes, Your Honor.

THE COURT: Any objection?

MR. FURR: No objection.

THE COURT: 92 will be admitted.

(Plaintiffs' Exhibit(s) 92 received in evidence.)

Q Dr. Coggins, is this one of the ETS Division Weekly Highlights on which you were copied?

A Yes, my name is on there, yes.

Q Okay. I'd like to turn over to the second page of the document and ask you about the paragraph entitled "Assistance to Public Issues Department." You see that, sir?

A Yes, I do.

Q The first sentence says, "Dr. Ogden," who we saw here the other day, "participated in a meeting held with representatives of Sara

Lee Corporation." And he discusses -- then it goes on to discuss the representatives from Sara Lee. And it says, "To discuss indoor air quality issues relating to possible implementation of a smoking restriction policy at Sara Lee."

Were you familiar with the activities of the ETS division to go out to companies who were concerned about smoking in the workplace and give Reynolds' view on what should be done?

A At the time this note was written, I was not involved in ETS, as such; I was performing inhalation studies.

Q But you were being kept up to date, were you not, by the division?

A Yes.

Q And you knew those things were going on, didn't you? You read it at least in 1990?

A I presume I read it, yes.

Q All right. Now going down a little bit, it says, "Dr. Ogden's role in the meeting was to discuss overall indoor air quality issues with emphasis on impacts due to inadequate ventilation as the primary cause in ETS as

but one symptom."

Do you see that, sir?

A Difficult to read, but yes.

MR. WESTBROOK: May I approach the witness? I have it highlighted.

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Q It is hard to read, sir. I was reading right there, sir.
A All right.
Q Then it says, "The meeting concluded with the Sara Lee representative agreeing to consider indoor air quality as the more central topic of concern and possibly contracting independent investigators, example, Gray Robertson of Healthy Buildings International, to study their facility and make recommendations." All right?
A Okay.
Q Doctor, are you aware that Gray Robertson has received and his company receives substantial funding from the tobacco industry with respect to ETS matters?
A I've heard the name, Healthy Buildings International. I've had a couple of very short meetings with him, I really don't know much about them.

Q In fact, you've relied on the Healthy Buildings International study in one of your scientific papers, haven't you?
A Yes. One of their scientists did an evaluation of the amounts of respirable suspended particulates, RSP, in I believe offices and restaurants and I used that as a reference in one of my published works, yes.
Q Would it surprise you, Doctor, that there are tobacco industry documents referring to Gray Robertson, who's represented here as an independent investigator, as one of the industry's big guns on ETS issues?
A I don't know what you mean by big guns. I don't know what you mean by funding. I don't even know who Gray Robertson is. I presume he's the director of this institute.
As far as I know, HBI went out and made measurements in buildings and offices. That's about all I know about them.
Q Now, Doctor, at the very bottom of the paragraph -- let me, if I may come back and help the reading --
First all, before I ask, can you see how many Reynolds representatives were at

this meeting? Could you take a look at that and tell me how many Reynolds representatives were at this meeting.
A I think I read three.
Q Who were those representatives?
A That would be Dr. Ogden, Mr. Tom Ogburn.
Q And what was his position at Reynolds?
A You know, I can't remember. He left. He was public relations, something like that, I'm not quite sure. He's no longer there.
Q He's a PR man?
A I think, yes.
Q And then who else?
A Dr. Carsmith.

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Q Dr. Carsmith was research and development?
A Yes.
Q Okay. Let's go down to the last paragraph. "One measure of the meeting's success was that the Sara Lee smoking policy proposal was never tabled for discussion." So that the Reynolds individuals reporting back here said that they considered that to be a success, that the smoking policy never came up to be discussed; correct?
A I can only say that I -- that's the way I

would read it but I don't know.
Q All right. Then continuing, "That they had a position statement already prepared was evident from a document overseen in Dr. Hayes' portfolio."
And Dr. Hayes is identified, is he not, as the medical director of Sara Lee?
A Uh-huh.
Q All right. So "a document overseen in Dr. Hayes' portfolio, which outlined restricting smoking to designated areas only."
Do you see that?
A Yes, I do.
Q All right. So from the document, and this report, Doctor, it's apparent, is it not, that someone from Reynolds had looked in this doctor's briefcase to see what he had in there; correct?
A That's the way I would read it, yes.
Q I think you told me once before it looked like somebody was looking in somebody else's briefcase.
A Yes.
Q Doesn't sound right, does it?

A I'm not sure about right. Maybe it was -- I wouldn't thought it was a normal occurrence but I wouldn't say it never happened.
Q Sounds like spying, doesn't it?
A I think that's maybe going a little far.
Q When you go to meetings, Doctor, with other scientists, do you try to look in their briefcases to see what they've got?
A I certainly do not.
Q All right, sir.
You mentioned on direct examination that part of your duties include interacting in some way with outside groups and you mentioned CIAR. Am I correct, you mentioned that?
A That's correct.
Q Now, this isn't really a group that's independent of the tobacco industry, is it?
A No, it's largely funded by the major U.S. tobacco companies.
Q And the tobacco companies sit on the board of directors of the CIAR; correct?
A There are two boards here. There's the

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Scientific Advisory Board and, as you say, there's the board of directors.

Q Okay. Let's talk about the board of directors. Board of directors. The board of directors consists of one or two representatives from each of the sponsoring tobacco companies; correct?
A That's correct.
Q And the board of directors has the purse strings; they decide whether to fund projects presented to them by the Scientific Advisory Board; is that correct?
A Not quite. I was recently involved in the procedure, so the Scientific Advisory Board presents to the board of directors their list of the best scientific projects. But in the case that I've been involved in -- probably, the two cases I've been involved in, the overall sum of money involved for these lists of the best projects is more than the annual budget. And so the board of directors meets to decide which ones to fund and which ones not to fund, yes.
Q Okay. So the board of directors has the purse strings. They decide who gets funded and who doesn't.
A After SAB review, yes.

Q Okay. Now, you mentioned the SAB. Scientific Advisory Board.
A That's right.
Q A lot of acronyms in this case. All right. So underneath the board of directors we have a SAB. And the SAB is composed of seven or eight scientists from various disciplines?
A I'm not sure about SAB reporting to the board of directors. I think, and I'm not totally sure, they report to the executive director.
Q Okay. Let's not worry about that. We know the money comes from here. Correct?
My question is: With the SAB, does the SAB consist of six or seven or eight scientists?
A I'm not sure the exact number but there are scientists, yes.
Q And they are respected scientists, in your view?
A Yes, I think that's true.
Q Okay. And are you aware, Dr. Coggins, that in 1994 a majority of the CIAR Scientific Advisory Board reported in response to a request from Congress that it believed that

ETS was a carcinogen? Are you aware of that?
A I was not aware of that. And I have, as we've discussed before, a lot of problems with that word.

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Q Dr. Coggins, I think you've told me in the past that you're familiar with the members of the CIAR, aren't you?
A They change, yes.
Q And sometimes you've sat on the board of directors for Dr. Spears when he couldn't make it; correct?
A Just recently, yes.
Q Let me show you, Doctor, a document from the house of representatives, U.S. Representatives of Energy and Commerce, ETS information package. And what I'd like you to do, Doctor, is turn in a few pages and tell me if you recognize the members of the Scientific Advisory Board.
A Thank you.
Q Three pages in. You see where the mission statement, then under that Science Advisory Board members?
A Yes, I do.

Q You recognize those people as generally the people who served on the Scientific Advisory Board or have served?
A I think some of them are still there. I'm not sure.
Q All right. And the second name is a Michael Guerin from Oak Ridge National Laboratory?
A Dr. Guerin, yes.
Q And you know Dr. Guerin?
A Yes, I do.
Q And you know a number of the other individuals on the board; do you not?
A Less well.
Q Okay. And then turn in the next page, which is the CIAR research agenda. See that, sir?
A Yes.
Q All right, now as part of your work now interacting with the CIAR, do you see the research agenda proposals?
A I see the research and review process.
Q Okay. You see that. All right. And let me ask you to look at the research and review process. Take a look at that and see if it's generally consistent with how you believe the research and review process

works for the CIAR SAB.
A This seems reasonable. Again, it was 1994. It may have changed today.
Q Is this generally consistent with how things operate?
A I think generally, yes.
Q And the research and review process, as the document records, it does state that studies recommended by the SAB are subject to the final approval of the board of directors; correct?
A Yes.
MR. WESTBROOK: Your Honor, we would move this document into evidence, the

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House of Representatives report containing the information about the CIAR SAB.

THE COURT: Be Plaintiffs' 93. Any objection?

MR. OHLEMEYER: Yes, Your Honor. It's hearsay and it's irrelevant. If they want to put opinions of these people before the jury, they should have brought these people to testify.

MR. WESTBROOK: This is a public report issued by the House of

Representatives of the Congress on the group which Dr. Coggins has been interacting.

MR. OHLEMEYER: Your Honor, it's hearsay and it's irrelevant.

THE COURT: Let me review the document here a minute. Why don't you go ahead, Mr. Westbrook, I'm going to look at this for a minute.

MR. WESTBROOK: Yes, sir.

THE COURT: I'll take it under advisement.

MR. WESTBROOK: All right.

BY MR. WESTBROOK:

Q Dr. Coggins, you said that you recently have sat with the CIAR?

A They have meetings every two or three months, and I've gone to some of those, yes.

Q And did you go in Dr. Spears' place or are you on the board now yourself?

A No, I'm not on the board. The last meeting I went to, both Dr. Spears and myself went.

Q Taking a look at the Science Advisory Board members in the document, the first name mentioned is William Cain, C-A-I-N. Do you know Dr. Cain?

A I'm sorry. Which page are you on?

Q It's three in, Doctor. One more page.

A Thank you. I know the name Dr. Cain. I'm not sure I ever met him.

Q We established you know Dr. Guerin, he's number two?

A Yes.

Q Irving Kessler, the third name?

A Never heard of him.

Q How about Morton Lippmann?

A Yes, I indeed.

Q And Genevieve Matanoski?

A Yes. I'm not sure I ever met her, but I certainly know her work.

Q All right. And Demetrios Moschandreas?

A Yes, I have met him.

Q And Mark Utell?

A I know the name, but I'm not sure I've ever met him.

Q Alfred Wolf?

A No.

Q And James Woods?

A No. I'm not sure if I know him either.

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Q Ph.D. All right. So for a number of these people, you have had some interaction with

them, including Dr. Guerin?
A No, I didn't say interaction. I said I was aware of their published work.
Q You've read their work as part of your review of the world literature?
A I've read their work, yes.
Q And are you familiar with the so-called 16 City study performed by Oak Ridge under contract to CIAR?
A I know a little bit about the 16 City study, but not very much.
Q And did you know that it was performed by Oak Ridge?
A I knew it was performed by Dr. Jenkins and that he recently published something on it, and it was funded by CIAR, yes.
Q And is it your view from your interaction with the CIAR that its Scientific Advisory Board consists of good and respected scientists?
A In general, I think that these are a very respectable group of people. As I say, this is four years old.
Q Yes, sir. And is the group today a respected group?

A I think that's true, yes.
Q In your interaction with the industry, have you ever heard anybody say, well, in the past we didn't have such a good SAB, and we've got to clean them out?
A Never heard such a statement, no.
Q As far as you know, the SAB has always been a respected group of scientists?
A No, I don't know that. But I know the group today, and I know a lot of the names on there and I have seen their published work, and they all seem very good scientists, yes.
MR. WESTBROOK: Your Honor, I would move this document.
THE COURT: Over objection, 93 will be admitted.
(Plaintiffs' Exhibit(s) 93 received in evidence.)
MR. WESTBROOK: Your Honor, may we pass copies to the jury?
THE COURT: All right.
Q By the way, Doctor, this Committee on Energy and Commerce, Subcommittee on Health and the Environment, headed by Henry Waxman, is that the committee that you once appeared before,

the Waxman committee?
A I appeared before the Waxman committee twice, I think. It may be the same one. I'm not sure.
Q All right. Let me direct your attention,

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Dr. Coggins, to the second page of the document entitled "Background Information."
A Yes.
Q You have that, sir? And going down, if we could, to the fourth paragraph under the heading "The Survey." I want to ask you about this particular situation here. "On July 6, 1994, the subcommittee sent each member of the CIAR Science Advisory Board a survey on the health effects of environmental tobacco smoke, ETS."
Now, this was before you got involved here, wasn't it? Were you involved with the CIAR then?
A In 1988, no.
Q No, 1994.
A I had the occasional meeting with them, yes.
Q Okay. The survey asked the members of the Science Advisory Board whether they agreed that ETS is a human lung carcinogen, a

serious and substantial public health threat to children, and a cause of cardiovascular disease and death. Then it goes on to talk about other questions asked of the survey respondents.
Now, the final paragraph says, "The survey results: Seven of the nine members of the Science Advisory Board responded to the survey." So seven out of the nine sent back the questionnaire. "A substantial consensus emerged on two points: One, six of the seven members agreed that ETS presents a serious and substantial public health threat to children."
Do you agree with that? Does it?
A I'm not sure that I agree with that, no.
Q And next, "Five of the seven members agreed that ETS is a human lung carcinogen." Do you agree with the majority of the Science Advisory Board, five out of seven members, that ETS is a human lung carcinogen, as they reported in the survey to Congress?
A No, I don't agree with that.
Q And do you see the very last page of the document is actually the survey results,

sir? Looks like this. And under the first statement, "ETS is a human lung carcinogen, agree," the number five is in there; correct?
A Yes, I guess it is, yes.
Q Okay, sir. Do you know if after 1994, the board of directors changed members of the SAB?
A The list I saw most recently has some of the same people on, but there are some that are no longer on.
Q Okay. And do you know, sir, if any of the five members who responded that ETS was a human lung carcinogen, have been taken off

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the board?
A I have no idea.
MR. WESTBROOK: Your Honor, I am going to go to another topic.
THE COURT: It might be a good time to take a lunch break. I think lunch is here. We will start again at 1:00.
(Standard admonition)
THE COURT: We are still in session.
When you are done with that exhibit,

you take your time, but pass them down, and the bailiff will pick it up.
MR. CASSELL: All rise.
THE COURT: All right. Doctor, you may step down.
(A lunch recess was taken.)
MR. CASSELL: All rise.
THE COURT: Be seated. All right. Jury back in its entirety.
State your name again, please.
THE WITNESS: Christopher Richard Emerson Coggins.
THE COURT: Thank you.
Mr. Westbrook.
MR. WESTBROOK: Thank you, Your Honor.
BY MR. WESTBROOK:
Q Hello again, Dr. Coggins.
A Hello.
Q How do you spell Gallaher?
A G-A-L-L-A-H-E-R.
Q You've mentioned a name this morning in direct examination, Auerbach. Do you know how you spell that?
A A-U-E-R-B-A-C-H.

Q Now, am I correct that in the mid-1970s Gallaher wanted you to do animal inhalation experiments with tobacco smoke; correct?
A Gallaher were doing animal inhalation studies with cigarette smoke.
Q Ones you carried on?
A But I continued doing the work, yes.
Q Now, when you were sponsored by Gallaher, did you have interaction with Gallaher scientists?
A Occasionally, I had a chance to visit scientists in their headquarters in London and also in their research facility, which was in Belfast, yes.
Q Okay. And I believe you said on direct examination that Gallaher wanted somebody available on the end of the telephone line to talk to?
A Yes. Most of the other scientists at the Battelle Lab were not English mother's tongue, so they wanted somebody like that.
Q You mentioned the Auerbach study this morning, and as I heard you over here, you

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were somewhat critical of that study. You thought that the way the dogs were exposed

might have stressed them and caused the cancer or something like that?
A Yeah, that's a rough approximation, yes.
Q Okay. Did the Gallaher folks, when they started to sponsor you in 1976 or so, tell you, Dr. Coggins, that they had examined the Auerbach results several years earlier, and they had concluded that the Auerbach results proved beyond a reasonable doubt that smoking caused cancer? Did they ever tell you that?
A No, the Gallaher people never told me anything about Auerbach at all.
MR. WESTBROOK: Your Honor, I would like to show Dr. Coggins an exhibit that is in evidence, Exhibit 35963.
THE COURT: All right.
MR. WESTBROOK: And 35963A, which is the cover letter for 35963.
THE COURT: Thank you.
BY MR. WESTBROOK:
Q Dr. Coggins, do you recognize the Gallaher company listed in the document there, the first document, the cover letter as the Gallaher for whom, or who sponsored your

work?
A I have no idea. I don't recognize the address, but it's a Gallaher Limited.
Q In London?
A This was not the address that I used to go to when I visited there, but this was 1970 so maybe they moved.
Q Were they in London?
A Not now, no.
Q Where were they in the '70s?
A I think they were in London, but not at this address.
Q All right. Now, this document which is in evidence, Doctor, I would like you to take a look at it, and I want to ask you two questions: Number one, first of all, does it concern Gallaher's review of the Auerbach study, so when you're looking, you can look at it like that? And then I'm going to ask you about some of the statements in the document. So if you'd take a minute.
Doctor, not to interrupt you, but have you read far enough to see that this is talking about the Auerbach dog experiment that you talked about on direct?

A It's very difficult to read. I read the cover letter, yes.
Q Is your copy readable, Doctor?
Doctor, perhaps to move this along, if you would turn to the page 3, which says "To

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sum up," which summarizes what's in the letter, and certainly you can look at whatever else you'd like to look at. I'm going to ask about that sentence, "to sum up," that paragraph summing up the conclusions.

A I see it. Okay.

Q Do you see where the Gallaher people said "To sum up, we are of the opinion that Auerbach's work proves beyond all reasonable doubt the causation of lung cancer by smoke." Do you see that, Doctor?

A Uh-hum.

Q Did Gallaher ever tell you that they believed when you came to start work on their sponsorship that Auerbach's work had proved beyond all reasonable doubt the causation of lung cancer by smoke?

A No. The Auerbach study was never mentioned to me when I arrived there some six years

after this.

Q Did they not share with you their scientific files on what they had done, the evaluations they had done of other research before you got started?

A I don't know what you mean what they had done. They didn't share this piece of work with me, no.

Q All right. Now, you said that you thought the way the dogs were exposed may have caused a trauma or stress that induced lung cancer. Would you look on page 1 of the actual Gallaher report, at the bottom of the page. Right here, Doctor, where they speak to that.

A Yes.

Q And they talk about the way that the dogs were smoked, and they go on to talk about some of the things you talked about, the stress of that, et cetera. And they conclude, do they not, "However, even when we bear this in mind, Auerbach's research is undoubtedly a significant step forward, and we have to remember that the control animals also tolerated a tracheostomy without undue

discomfort and trauma and there was no evidence that these animals showed any signs of precancerous or cancerous changes." Do you see that?

A Yes.

Q So they looked at the question you talked about on direct, and they said, well, the animal -- the other animals, the control animals had the same procedure and they didn't get cancer, so it couldn't have been the procedure that caused their cancer. That's what they're saying in plain English, aren't they?

A No. I think that what they're really saying

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here is that the tracheostomy in the untreated animals appear to have no undue effect. But when you are putting vast amounts of cigarette smoke through it, it may well be a very different procedure. Just a tracheostomy or a tracheotomy, just a hole in the trachea without anything going through it, may not cause an infection. Because of the irritation with cigarette smoke being associated with it, I think that's a very difficult comparison to make.

Q You didn't know until I had shown this to you a few minutes ago that Gallaher thought Auerbach proved the issue beyond all reasonable doubt?
A I have not seen this before, no.
Q Now, Doctor, you performed some animal experiments whose results you haven't published; correct?
A That's true.
Q And other researchers do so as well; right?
A I presume so, but I don't know.
Q You presume so, you don't know it because what's not published, outside scientists don't ever get to see and evaluate; correct?
A That's right.
Q Have you ever performed an animal inhalation study for the tobacco industry using a commercial cigarette, a regular cigarette that is sold at the 7-11?
A No.
Q Now, am I correct that you stopped doing animal studies in 1992?
A Approximately, that's right, yes.
Q And before that, on the issue of secondhand smoke or environmental tobacco smoke, you

had done two studies.
A I'm sorry. I missed that.
Q Before you stopped doing animal experiments in 1992, you had done two studies on environmental tobacco smoke?
A Two large studies, yes, and a smaller one.
Q Would you call it three studies?
A We did a smaller study that we didn't discuss this morning.
Q Was it on environmental tobacco smoke?
A Yes, it was.
Q Let's call it three. Now, you mentioned somebody else this morning in response to direct questioning, a Dr. Witschi?
A Yes.
Q How do you spell that?
A W-I-T-S-C-H-I.
Q And you mentioned that Dr. Witschi has done three experiments with environmental tobacco smoke; correct?
A That's correct.
Q You did your experiments when you were working for the tobacco industry; right?

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A Yes.
Q Okay. Does Dr. Witschi work for the tobacco

industry?
A No, I don't think so.
Q Was he an academic out in California somewhere?
A Yes.
Q University of California?
A I think that's correct, yes.
Q So he works at a university.
A That's right.
Q Okay. Your three experiments, did you use rats in all three?
A Yes, we did.
Q You used rats. His three experiments, did he use another rodent, mice?
A He used mice.
Q Now, you actually used in your experiments sidestream smoke; correct?
A We used, as I discussed this morning, aged and diluted sidestream smoke, yes.
Q And you pointed out, that's different from environmental tobacco smoke because it doesn't have the exhaled mainstream component; correct?
A That's correct.
Q Now, Dr. Witschi, he actually used

environmental tobacco smoke as he manufactured it with about 89 percent of what you used, and then about 11 percent exhaled mainstream smoke; correct?
A Dr. Witschi used fresh sidestream with some fresh mainstream, but I think at concentrations which were so high, they would not be considered environmental tobacco smoke.
Q But it had the same proportions of the mixture, didn't it? He used some sidestream and some mainstream.
A That's true.
Q And you didn't use any exhaled mainstream in your experiments?
A Neither did he. He used non-exhaled mainstream.
Q But he used a percentage of mainstream.
A That's right.
Q Now, you found no tumors in your experiments; correct?
A That's correct.
Q And these studies went through the normal Reynolds' review process before they came out?

A That's right.
Q Okay. All right. And, Dr. Witschi, we'll talk about that. He found tumors in let's call it experiments 2 and 3?
A Correct.

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Source: https://www.industrydocuments.ucsf.edu/docs/gyxd0001

Q Okay. And to your knowledge, Dr. Witschi's work doesn't have any industry review process, does it?
A I have no idea.
Q You didn't see Dr. Witschi's work going through the Reynolds' review process before it was published, did you?
A I don't think so.
Q Doctor, you said that part of your job recently has been to review the world's literature and to keep up on it, I guess, since 1992. You've really made a comprehensive effort to read everything that's going on.
A I would say since earlier than that, but yes.
Q And you've gone back and looked at other things in the published literature as well; correct?
A Yes.

Q Have you ever seen a study by a Reynolds' scientist, Lorillard scientist, Brown & Williamson scientist, any other American tobacco company scientist, any study that said in print published for the world tobacco smoke causes lung cancer?
A No, I don't think I have.
Q Have you seen studies, in fact, a number of studies, by scientists not connected with the tobacco industry published in the literature that say tobacco smoke causes lung cancer?
A The only two papers that I'm aware of involving experimental animals are these two you have mentioned here, in experimental animals.
Q I'm not confining that question to experimental animals. I mean scientists who consider all the evidence. I mean, you don't confine your reading to just experimental animals, do you?
A No. I was understanding you to be talking of these studies here.
Q Have you seen any study by an industry scientist in any form that said yes, tobacco

smoke causes lung cancer published out for the world to see?
A No. I think as we discussed this morning, the problem comes in the definition of the word "cause." I can only give my answer to what that word means as a definition.
Q Doctor, to save a few minutes, I have prepared a Westbrook chart of the comparison between a human and a rodent, and I want to ask you if we could --
MR. MOTLEY: Judge, I may have to object to this one.
MR. WESTBROOK: Do you object to that?

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MR. OHLEMEYER: Your Honor, I think --

BY MR. WESTBROOK:

Q Doctor, let's talk about rodents and rats, if you want to be -- you're most familiar with rats?

A I have done work with rats and mice.

Q Okay. Rats live about two years?

A Uh-hum.

Q Maybe two and a half?

A Maybe.

Q All right. People, life span, 80 years these days, if you're lucky?

A Probably.

Q We hope so. Now, rats breathe through their nose; correct?

A Rats are what's called obligate nose breathers. They have to breathe through their nose, as they really don't do any mouth breathing.

Q Obligate like obligation?

A Yes.

Q Nose, yes; mouth, they cannot breathe through their mouth.

A I think that's correct.

Q All right. People can breathe, obviously, through their noses, and people also breathe through their mouth; correct?

A Yes.

Q For instance, people are more likely to breathe through their mouth on exertion, right, when you get exercising and something like that?

A That's right.

Q Because your nose can't bring in enough air?

A I presume that's it, yes.

Q On exertion. People breathe through their mouth if they have a bad cold, nasal passages get stuffed up and people compensate by breathing through their mouth more, don't they?

A I imagine so, yes.

Q People breathe through their mouth when they sigh? People go (indicating), somebody sighs, they take a breath through their mouth; correct?

A Yes.

Q People breathe through their mouth when they yawn?

A I'm not sure about that.

Q How about before they cough? Before you cough, don't you go (indicating).

Okay. There may be some others, but let's stop there.

Now, when people breathe through their mouth, they bypass this portion of our body's defense systems up in the nasal passages; correct? The hair, the mucous and the twists and turns of the nose; right?

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A That's true.
Q That doesn't happen on the rodent,

everything comes in and goes through whatever the protective measures are there in the nasal passages; correct?
A Okay.
Q Now -- by the way, are there any differences between the mouse and the rat in that respect? Are they both obligate nose breathers?
A No. I think they're both the same.
Q Okay. So both the same.
Now, in your experiments you've seen, Doctor, have you not, that when you first exposed the rats to smoke, they don't like it, do they?
A Rats and mice, too, are very irritated by large quantities of mainstream smoke, yes.
Q So they try to avoid it. And one thing they try to do initially is they try to slow down their breathing pattern, don't they?
A That's what we discussed this morning, yes.
Q Okay. And then so they'll try to breathe slower, and then after a while, I think you've done a study which shows that rats, and mice maybe, but rats will pick up their breathing pattern, they'll breathe faster?

A That's right too.
Q And they'll also on occasion lower the amount they take in? I think I called it shallow breathing. You like to call it low tidal volume; correct?
A Yes, that's right.
Q So rats are breathing more, but they're breathing more shallowly than they did originally; correct?
A Yes.
Q And you think, do you not, from your work, that that's a response to the smoke, the rats are trying to avoid that smoke, aren't they?
A That's kind of building up a sign that they know what's going on, but we can just describe the changes. Whether the rats know it or not, I don't know.
Q And your work with rats, Doctor, is not meant in any way to relate to human smoking behavior, is it, how people smoke?
A No. I think the way humans smoke cigarettes is very different from the way the systems I have used to expose animals to mainstream smoke. Humans smoke in a very different

way.
Q Now, you mentioned the Witschi papers. Let's talk about those papers for just a few minutes. In the first study by Dr. Witschi, he exposed his mice to this environmental

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tobacco smoke mixture, at least in the proportions, for five months, and then he let them sit for a period of several months to see what would happen; correct?
A I think that's right, yes.
Q All right. And after he let them sit for a while, he saw a statistically significant increase in the number of tumors in this smoke-exposed mice versus the control mice.
A Could I just ask for a correction there? Are you talking of the first of these two studies, as opposed to his first of three?
Q I'm talking about the studies 2 and 3.
A In study 2, as we described, he exposed the animals for the period of time. At the end of that exposure, the incidence was the same. After the waiting period, there seemed to be an increase in the smoke-exposed group, yes.
Q In fact, Dr. Witschi found that 80 percent,

approximately, of the exposed got tumors, and something like, what, 35 percent of the controls, and he found that to be a statistically significant increase, didn't he?
A That was his finding, yes.
Q Okay. I think you've told me in the past that you thought that parts of this study, too, were good science, didn't you?
A I think parts of it are good science, and I think parts of it are not quite so good.
Q And it wouldn't surprise you, Doctor, that other scientists might say the same thing about your studies?
A I'm sure.
Q All right. And this Witschi study, the first one we're talking about, No. 2 of the series, was in the peer-reviewed scientific literature, wasn't it?
A I think so, yes.
Q Now, Witschi did another study, a third study you didn't talk about on direct, did you?
A No.
Q And in that study, Dr. Witschi filtered the

environmental tobacco smoke to remove a vast amount of the particulate matter so I think the particulates were down to like .1, weren't they?
A It was very low.
Q Very low. And even when he exposed those mice to the very low amount of particulate, and then he analyzed his data, he again found statistically significant increases in the tumors in the mice, didn't he?
A Not at the end of the experiment but at the end of the waiting period after the experiment, yes.
Q Well, you define the end of the experiment

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as the exposure, but Dr. Witschi defined his experiment as exposure, you wait and see what happens, and that's where he counted and there he found, even with the filtered ETS, down to .1 -- which was the same number I think that you used as an exposure in buildings, isn't it, .1?
A I'm not sure. I'm not sure about that.
Q Isn't that the number?
A We used that as our lowest concentration, but, in theory, if he's filtering the smoke

as he is saying, he shouldn't have anything there.
Q But he filtered it down to .1.
A I think.
Q He didn't claim he got it all out but he said he was going to clean up this ETS as much as he could and he got significant amounts of tumors after the mice were exposed, then he waited and he looked and, lo and behold, tumors.
A That's right.
Q And you've published with Witschi, haven't you?
A Yes, I have.
Q He's no quack, is he?
A I have my problems with some of Dr. Witschi's approaches, yes.
Q Well, I can see you have some problems with the experiments, but he's not some kind of mad scientist, is he?
A No, I don't think so, no.
Q Now, are you familiar with a study by Essenberg in 1952?
A Yes, I am.
Q Exposing mice to tobacco smoke?

A Yes.
Q And Essenback got tumors in those animals, didn't he?
A This is Essenberg, I believe.
Q Thank you for that correction.
A Well, I just want to make sure we have it correct.
Q I appreciate it.
A I believe in 1952, the study that I have read, it was very difficult to see exactly what they did in that they didn't describe their exposure apparatus at all. And they used, again, the strain of mouse that Dr. Witschi used, too.
Q And looking over to rats, Dr. Dalby and his colleagues in 1980, they exposed rats to tobacco smoke and they got tumors, didn't they, in their exposed rats more than in the controls?
A Yes. Dr. Dalby performed a study where the total number of tumors was different in mainstream than in sidestream -- than in controls.

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Q So the medical and scientific literature does have reports, including very recently

on ETS, but reports that experimental animals exposed to tobacco smoke get lung tumors. That's in the literature, isn't it?
A They are indeed in the literature. I have problems with those studies.
Q Doctor, your animal of choice over your career has been rats, hasn't it?
A I think inhalation toxicology in general uses rats, yes.
Q Are you aware that in 1969 Reynolds scientists internally reported that rats weren't a good model?
A No, I'm not aware of that.
Q When you were at Reynolds, did you have access to the laboratory research files if you cared to look?
A I did.
Q You don't now because you've gone to Lorillard, obviously.
A Correct.
Q Let me show you a document. Exhibit 9973.
MR. FURR: Is this in evidence?
MR. WESTBROOK: No, it's not in evidence, as far as I know, yet.
Your Honor, we're going to move this

document into evidence from the files of the RJ Reynolds Tobacco Company.
MR. OHLEMEYER: Lack of foundation, Your Honor.
MR. WESTBROOK: Your Honor, the document concerns experimental inhalation from the files of Reynolds, the files that Dr. Coggins said he had access to if he cared to look.
THE COURT: Well, I'm not sure that alone gives it foundation, Counsel.
MR. WESTBROOK: And it was produced as a record of the RJ Reynolds Company, Your Honor.
MR. OHLEMEYER: Same objection.
MR. MOTLEY: Your Honor, he also testified that there were only X number of studies. It goes to the credibility of the information he had about such opinions before the jury.
THE COURT: What's your objection, Mr. Ohlemeyer?
MR. OHLEMEYER: Lack of foundation, Your Honor.
THE COURT: Authenticity?

MR. OHLEMEYER: No. The witness has read and reviewed, relied upon it and formed any opinions about it.
THE COURT: Well, it goes, as Mr. Motley points out, he did testify to the

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number of studies, so the objection is overruled. 9973 will be admitted.

(Plaintiffs' Exhibit(s) 9973 received in evidence.)

MR. WESTBROOK: Thank you, Your Honor.

Q Dr. Coggins, taking a look at 9973, do you see the title is "Initial Attempts at Exposing Rabbits to Hole Cigarette Smoke"?

A Yes, I do.

Q And I wanted to ask you to take a look at page 2 under introduction to the comments about the rat, and I highlighted the sentence here. "Why the Reynolds scientists chose a rabbit." It says, "The rabbit was chosen because the only other choice was the rat or guinea pig; both small rodents and poor animals for pulmonary studies."

Do you see that there?

A Yes.

Q When you were at Reynolds, sir, did you know that this report had been written and was in the files saying that rats were poor animals for pulmonary studies?

A No, I have not seen this before.

Q Is that something you disagree with?

A Yes.

Q Dr. Coggins, did you know that before you came to Reynolds, had you heard that Reynolds had, for a period, closed down its biological research on animals?

A This I believe was before I joined Reynolds, yes.

Q Dr. Coggins, did you know Dr. Alan Rodgman at Reynolds?

A Yes, I do.

Q And what was his position while you were at Reynolds?

A I'm not sure. He retired during my time there. I'm not sure what he was when I was there.

Q He was a big wig in research, wasn't he?

A I think that's right, yes.

Q Whether he was director or director emeritus, or senior director, he was the top

man at research, was he not?

A I think he was a senior scientist, yes.

Q Dr. Coggins, let me show you a document authored by Dr. Rodgman at Reynolds in 1962.

MR. WESTBROOK: This is in evidence, Your Honor, 14333.

THE COURT: Thank you.

Q And Dr. Coggins, what I'm going to ask you about is the discussion on page 13 about Reynolds scientists publishing or not publishing their research. Page 13, sir.

Let me, if I can help you, Doctor, show you, members of the research department.

A Okay. Yeah.

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Q All right. And Dr. Rodgman speaks as follows -- and I want to ask you about this sentence. "Members of this research department have studied in detail cigarette smoke composition. Some of the findings have been published. However, much data remain unpublished because they are concerned with carcinogenic or co-carcinogenic compounds."

Dr. Coggins, were you aware when you came to Reynolds that the company had not

published scientific data because the experiments involved in those -- in that data concerned carcinogenic or co-carcinogenic compounds?

A I have not seen this paper before. However, I do know of a large number of publications from Reynolds in the period between 1962 and when I arrived in '85.

Q How many papers does Dr. Rodgman reference that Reynolds had not published because they concerned carcinogenic data? They're right there, aren't they, numbered, 1, 2, 3, 4 -- well, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16 papers he references by number, doesn't he?

A I didn't count but okay.

Q Or approximately so.

Had the policy changed by the time you got there, Doctor, that experiments and results involving carcinogenic compounds could be published? Had the policy changed?

A I have a big problem with the use of the word "carcinogen" or "carcinogenic activity" because, as we've discussed before, it isn't an integral part of a chemical like

molecular weight. It varies with other parameters. And as such, I believe that you can't just use it in its entirety.

You have to relate the carcinogenic nature of the material to a variety of other factors, including the animals that are being involved, the route of administration. Most importantly, the dose. And then the target all. I don't think you can just use the word "carcinogenic compound" as Dr. Rodgman did, I think rather simplistically, in 1962.

Q Doctor, is it proper in the scientific world to withhold from publication data because the data concerns carcinogenic or carcinogenic compounds? Is that a reason not to put the data in the published literature so other scientists can see it?

A I don't know whether this was withheld or not. That's Dr. Rodgman's statement. I don't know whether this was the policy, whether it's Dr. Rodgman's reading, or whether it is anything else. In 1962, I

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really don't know.
Q There's no question he says "much data

remain unpublished because they're concerned with carcinogenic or co-carcinogenic compounds," is there? There's no question he said that.
A As I said, since 1962, Reynolds R & D published a large number of papers.
Q Dr. Coggins, rats live two and a half years. Have you -- in your ETS studies, is it correct that the longest you ever exposed the rats to this sidestream was 90 days?
A 90 days, yes, sir.
Q Okay. Dr. Coggins, as far as you're concerned, from a scientific standpoint, it would be fine for people to smoke in any building without restriction, isn't that correct, except for maybe elevators or a closet, but you're not concerned from a scientific standpoint from your work and the work you've seen about people smoking in a building for any reason, are you?
A I think some of the work that I have performed and some of the epidemiology studies that I have read would indicate that exposure to ETS is not a risk factor for disease.

However, that may not be the reason for smoking to be banned for other reasons.
Q Well, do you have any scientific concern if everybody in every building was smoking, but for annoyance, do you have any scientific concern that there is any health risk at all?
A Any at all are very large words. I would say that the papers I have read indicate no increase in epidemiological risk and, combined with my rat inhalation studies, I would say there is no risk.
Q Now, you mentioned on direct that you did some work on the Premier monograph, the book about the Premier cigarette?
A Yes.
Q And in the Premier cigarette, the work that you did, am I correct that you exposed some animals to smoke or whatever came off Premier to see what the reactions would be? Did you do that?
A Yes. As we described this morning, we exposed rats to the mainstream smoke from Premier cigarettes that only heated the tobacco and from reference cigarettes that

burned the tobacco.
Q And that's this book that you wrote a chapter in?
A I wrote one chapter in the book, yes.
Q Now, Doctor, to your knowledge, had Reynolds

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ever published a book like this, instead of new cigarette prototypes that heat instead of burn, have they ever published a book like this, old cigarettes that burn tobacco and compare the reactions you got from one cigarette to another? Did they ever publish something like this and put it out with the fanfare that this came out?

A I'm sorry. I don't understand your question.

Q Had Reynolds ever prepared a monograph like this for the old cigarettes?

A You mean combining data on the chemistry of old?

Q An incentive study that was done like this for Premier, was it ever done on Winston and put out like this?

A I don't think so.

Q Camel?

A Not to my knowledge.

Q Dr. Coggins, am I correct that in your animal experiments you used what's called a reference cigarette?

A Yes. There are a series of reference cigarettes available from the University of Kentucky, and we picked one of those, yes.

Q Now, the reference cigarettes, they don't have the flavorings and additives that commercial cigarettes do, do they?

A No. Reference cigarettes are constructed, as I say, by the University of Kentucky to approximate to an average, if you like, of American cigarettes.

Q Doctor, as you mentioned on direct, you've confined your actual laboratory science to animal experiments. But you're aware, are you not, that there are scientists in other fields who have gotten together to study this issue of cigarette smoke and lung cancer and brought together a number of disciplines, the epidemiology, the toxicology, the chemistry, the biology, and have come together in groups like the Surgeon General's group and issued reports; correct?

A Yes.

Q And without hauling them all up here, I've got several boxes of them, is it correct to say -- and I could stack up a stack of books and reports which would obscure you from the jury -- that all say from various government organizations that cigarette smoking causes lung cancer? I mean, you wouldn't doubt that, would you?

A I think you could probably do that.

Q And you just simply disagree with those conclusions?

A No, not at all. I think that the raw data enclosed in, for example, the '86 report on

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secondhand smoke, I agree with much of the science. What I do not agree with is the application of that science to policy. The scientific studies are, in general, quite good. But then an extrapolation is made from that science to what public health policy should be. That's what I disagree with.

Q You disagree with the findings that secondhand smoke causes lung cancer. You just disagreed with that.

A I'm not sure which finding you're talking of.

Q The Surgeon General's Report, the EPA Report, the California EPA Report?

A I don't think any of those three reports show me that the epidemiology of spousal smoking or of workplace exposure to environmental tobacco smoke raises the relative risk for lung cancer.

Q So you disagree.

A I do.

Q Now, in your position as senior vice president at Lorillard, your current position, do you have access to the Lorillard files?

A I'm sure I do.

Q Now, I think I heard you say on direct that you really don't know what your research department is doing. At least in some areas. Did you say that?

A That's true.

Q That's something you're going to get a handle on when you can?

A That's my plan, yes.

Q All right. Let me show you a document from

the Lorillard files, sir. It's Exhibit 35493.

MR. WESTBROOK: Your Honor, we move Exhibit 35493 into evidence, a Lorillard memorandum produced by that company dated May 18, 1981.

MR. OHLEMEYER: Your Honor, lack of foundation with this witness. It appears to be some sort of advertising document. And I don't think we've established that this witness has worked with the advertising department.

MR. WESTBROOK: Your Honor, it's a document produced by the company for which he is a senior vice president reporting to Dr. Spears who was the chief executive officer.

THE COURT: Well, Mr. Ohlemeyer is correct at this point. You may want to do some foundation, if you can, Counselor.

BY MR. WESTBROOK:

Q Dr. Coggins, from your working with Dr. Spears, conversations with people in

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Lorillard, have you come to know that
Lorillard investigated a low sidestream

smoke cigarette in the early 1980s?
A No, I do not know that.
Q Haven't heard anything about that?
A No, sir.
Q Is that subject a subject that would be of interest to you as you move ahead to try to learn what Lorillard has done over the years in research?
A It may be. Clearly, I could go back a long way. We're a very old company.
Q Dr. Coggins, am I correct that you don't have any animal experiments underway or in mind at the present time?
A Actually, we do have some underway at the moment.
Q Are they going to look at the ETS issue?
A No, they're not.
MR. WESTBROOK: Thank you, Dr. Coggins.
THE WITNESS: Thank you.
THE COURT: Redirect, Mr. Ohlemeyer?
MR. OHLEMEYER: Yes, Your Honor.

REDIRECT EXAMINATION
BY MR. OHLEMEYER:

Q Dr. Coggins, if Mr. Westbrook brought all that paper in here and stacked it up, with respect to the data, the scientific data in that material, would we be looking at mostly epidemiological data or animal inhalation toxicology data?
A I think it would be very largely epidemiology data.
Q And is there a difference between epidemiology data and animal toxicology or inhalation toxicology?
A Yes. I think epidemiology data is a relatively soft form of experimental data. It's very difficult to replicate, very difficult to duplicate, and I think it's a very soft science.
Q What would you find in all of that information about inhalation toxicology as it relates to cigarette smoke and lung cancer?
A You'd find very little.
Q Why is that?
A I'm not sure.
Q Is it fair to say that you would find references even in the Surgeon General's

Report to the fact that when people try to do inhalation experiments with animals, they typically don't produce --
A I think I have seen that.
MR. WESTBROOK: Objection, Your

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Honor, leading.
THE COURT: It was leading.
Q What, if anything, do you recall the Surgeon General saying about the results of the types of inhalation toxicology experiments you've told us about with respect to cigarette smoke?
A I think I recall seeing somewhere statements along the line that it is very difficult, if not impossible, to induce lung cancer in experimental animals as a consequence of exposure to cigarette smoke. Something along those lines.
Q And what information does that provide to you as a scientist when you are trying to assess or determine the relationship between cigarette smoking and disease?
A It means that to me the epidemiology data are pointing in one direction and that hypothesis generated by epidemiology is not

being confirmed by the animal data. So we don't have a convergence of the data.
Q Explain to us what you mean by there's not a convergence of the data.
A There's a, as we discussed this morning, a risk factor for cigarette smoking and, let's say, lung cancer. That epidemiological finding allows you to generate the hypothesis, does cigarette smoke produce lung tumors in animals as a result of cigarette smoke exposure? Because epidemiology can only look at broad associations. It cannot prove causality.
Experimental models -- and by a series of experimental models and a series of epidemiological data would allow to you have a convergence of different sets of data to a general conclusion or causality. We don't have that.
Q In other areas of science when you're trying to make those kinds of determinations, do you typically look for that kind of convergence?
A I think you would, but I'm not an expert in areas other than cigarette smoking.

Q Do politicians sometimes use something or accept something less than a convergence of data to make public policy decisions on those types of issues?
MR. WESTBROOK: Objection, Your Honor, as to what politicians do from Dr. Coggins.
MR. OHLEMEYER: Well, we've got questions, Your Honor --
THE COURT: Overruled.
A For example, the 1986 Surgeon General's Report makes some statements on the science and then very quickly moves from science to public health policy. And the vast -- a

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large part of that particular Surgeon General's Report is related to policy, not to science.

Q Is there a difference between determining a scientific fact and making a determination of public policy?

A Yes. I think scientists are concerned with data. The policy is way beyond me. I don't understand policy.

Q With respect to the exhibit that was put in front of you, Plaintiffs' 14333, page 13 of

that Rodgman memo, there's also a list of the findings that have been published; right?

A That's right.

Q And there are, I count, 12 references.

A Yes.

Q As of that point in time.

A As of '82, yes.

Q Now --

A '62, excuse me. '62.

Q Now, Dr. Coggins, you mentioned something about reference cigarettes. Why do you use reference cigarettes in these types of experiments?

A Reference cigarettes allow you to have a common source for researchers throughout the world. It may be that different research groups have access to different kinds of branded cigarettes that are not necessarily the same throughout the country or throughout different countries.

The 1RF4 is a cigarette that was generated by the University of Kentucky along with several others to formulate a standard so that we would all be using the

same basic cigarette for testing, not using a different model here and a different model there.

Q Who uses those reference cigarettes when they do animal inhalation toxicology studies?

A Virtually everyone.

Q When you say everyone, define who everyone is.

A For example, the work that we described by Dr. Witschi, he used the same cigarette as we used in my studies.

Q What about when the government or the Surgeon General or other people -- I guess the Surgeon General doesn't do that kind of research -- when the government or the National Cancer Institute does research, do they use those?

A They would tend to use reference cigarettes yes, sir, yes.

Q With respect to Dr. Witschi, am I correct you know Dr. Witschi?

A Yes, I do.

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Q And you've actually published papers with Dr. Witschi?

A I have.
Q And shared information with him --
A That's right.
Q -- about your areas of expertise.
Why -- what's the difference between using mice as opposed to rats in this kind of experiment?
A There are very few strains of rat. Basically a rat, within reason, is virtually the same as the next rat. Mice, on the other hand, have been genetically inbred and inbred.
Q May I interrupt you?
A Sure.
Q Why is it important that one type of rat is the same as the next type of rat as the next type of rat?
A To obtain consistency of results. Mice, on the other hand, have been genetically inbred so that there are hundreds of different strains of mice used for different purposes.
Dr. Witschi picked a rather strange strain of mouse, as I say, that was used to study cleft palate that has a very high incidence of lung cancer, so that virtually

all animals by a year old have lung cancer. So that when you have a very high background of lung cancer, it's extremely difficult to work out whether you have an increase or a decrease as a result of experimental treatment. They all have lung cancer. So his choice of a mouse strain, I think, is rather questionable, of the AJ mouse strain.
Q What about the route of exposure. What route of exposure did he use in his experiment?
A The system that Dr. Witschi used basically was a large chamber, let's say the size of this TV, maybe twice the size of the TV, into which he just put mice. And at the end of the day, he took them out and did his tests on them. This allowed a second route of administration other than inhalation.
What happens when you put these mice in a large chamber like that, is that large amounts of the tar are deposited on the skin. Some of that will go through the skin. You remember we talked about oral this morning, and some of it will be licked off the skin by the rat -- by the mice. So

they're going to get inhalation of ETS, they're going to get oral ingestion of ETS, and they're going to get dermal absorption of ETS, one of which is appropriate and two clearly is not an appropriate route of

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administration.
The study I defined this morning, and I omitted to point out, was we placed animals inside tubes that prevented the oral and the dermal absorption of materials, of the experimental materials.
Q And is that a way -- is that considered a control or a way to avoid a confounder?
A We are as certain as we can be that inhalation is the only route of administration as opposed to eating this tar as opposed to skin absorption of the tar.
Q What about the amount or the levels of exposure; how did that compare?
A If you'll recall, we used .1, 1, and 10 milligrams of cubic meter. We think .1 is a high real world estimate. Dr. Witschi in his study used 87 milligrams of cubic meter. I think that's getting to be almost as concentrated as mainstream smoke. He's

clearly using a completely inappropriate concentration of cigarette smoke.
Q How does his concentration compare to real world exposure levels?
A It's probably on the order of two and a half thousand times higher.
Q And is that a fact that he points out in his paper?
A I think he may not have that exact figure, but he admits it's a very, very large exaggeration.
Q And what about his animals with respect to weight loss?
A During Dr. Witschi's exposures, his animals lost weight during the smoke exposure part. Then as soon as he stopped exposing, their weight started to gain again. And I'm wondering whether this depressing weight and then rebouncing back may have something to do with this strange effect of the tumors being present at different concentrations at the end of the experiment as opposed to the end of their reversibility phase. That's just a theory.
Q Let me read to you a sentence from one of

Dr. Witschi's papers and ask you to explain it to us. He says -- and let me ask you if you're familiar with this statement too. "The usefulness of our," meaning his animal model, "study of human tobacco smoke-induced lung cancer remains to be established"?
A I think he has generated a hypothesis for how these very high concentrations of very concentrated ETS can affect lung tumor genesis in AJ mice. That's all he can talk to. I think it's going to be very difficult to make any extrapolations to anything else.
Q So even today as we speak, people like Dr. Witschi are studying the issue of

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environmental tobacco smoke and its relationship to disease?
A Yes, that's right.
Q So in a manner of speaking, people like Dr. Witschi didn't stop looking at the issue after 1986.
A No.
Q Now, with respect to the exhibit that was put in front of you before lunch, 2815, the CIAR survey. Do you remember that?
A Yes, sir. 2815.

Q By the way, when you provide information to Congress, do you consider that a performance?
A It was hard work, but no, it was not a performance. It was a scientific presentation.
Q Now, with respect to Plaintiffs' Exhibit 2815, the final page of that exhibit contains a number of statements about the relationship between ETS and certain risks to health; right?
A That's right.
Q And then there are columns; agree, disagree, and no opinion.
A Yes.
Q And presumably what they did was they asked each of these individuals on this Scientific Advisory Board what their opinion was on these subjects?
A I presume that's what they did.
Q Is there any issue where there is unanimity of opinion?
A No.
Q As a scientist, what does that tell you about the issue in question?

A That there's a lot of uncertainty.
Q Dr. Coggins, with respect to the Auerbach beagle study, is it fair to say that people form opinions or make judgments about scientific data at a particular point in time that are subject to change over time?
A Yes, that's true.
Q And what basis or for what reasons do those judgments about scientific data change?
A A very good example is when more studies are published. That if you form an opinion in year 1998, and studies appear with different opinions in 1999 and thereafter, then your opinion may well change.
Q Am I correct that a variety of opinions about that Auerbach data were published between the time those studies were published, the time you got to Gallaher, and even by the time you got to Reynolds?
MR. WESTBROOK: Objection, leading again, Your Honor.
THE COURT: Overruled. You may answer.

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A Not only opinions, opinions were indeed presented, but other studies were performed

that I think didn't have the same set of results.
Q And to your knowledge were the Auerbach studies ever reproduced?
A That was really my point. I don't think that they were.
Q What's the importance of trying to reproduce a scientific experiment?
A Certainly to make sure that the first study wasn't just an aberration, that there was something wrong. I like to see studies repeated perhaps more than once, but in general, the dog studies that have been performed after Dr. Auerbach's work, I don't think have confirmed his earlier findings.
Q Now, Mr. Westbrook asked you about the media. From time to time, has the media expressed an interest in either your work or your company's work?
A I don't think so, no.
Q Have you been called upon and asked upon -- have you been called upon or asked to make presentations to the media from time to time?
A Not while I've been with Lorillard, no.

Q What about at Reynolds?
A Did they ever contact me?
Q Were you ever involved in making a presentation to the media?
A Yes.
Q And that concerned the work you had done at Reynolds?
A It concerned both my work at Reynolds and the interpretation of other scientific papers that I had read, yes.
Q And do you know who David Burns is?
A Yes, I do.
Q Have you ever seen him on television?
MR. WESTBROOK: Objection, Your Honor. I didn't ask about Dr. Burns.
THE COURT: Sustained.
Q Do you think other scientists who are involved in issues that generate interest from the media from time to time are involved in things like media training or media issues?
A I have no idea whether they are or are not.
MR. OHLEMEYER: Thank you, Doctor. That's all I have.
THE WITNESS: Thank you.

THE COURT: Recross, Mr. Westbrook?
MR. FURR: Your Honor, could I have permission to ask just a few questions on behalf of RJ Reynolds?
THE COURT: Go ahead, Counselor.

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MR. FURR: Thank you.
REDIRECT EXAMINATION,
BY MR. FURR:
Q Good afternoon, Dr. Coggins.
A Good afternoon.
Q Do you recall Mr. Westbrook raising with you some issues regarding lawyer involvement in science?
A Yes, sir.
Q I want to ask you some questions on that topic that pertain to the period in which you were employed by the RJ Reynolds Tobacco Company.
A Okay.
Q During that period, Dr. Coggins, did any lawyer, including the lawyer employed inside the tobacco company or an outside lawyer that represented the tobacco company, ever ask you to destroy scientific data?
A No, sir.

Q During that period did any lawyer, an inside lawyer or an outside lawyer, ever ask you to distort or change the findings of your scientific experiments?
A Absolutely not.
Q Did any lawyer ever attempt to suppress information that you had generated in a scientific experiment?
A No.
Q Did any lawyer ever ask you to do anything whatsoever that you considered to be scientifically inappropriate?
A No, they did not.
Q Dr. Coggins, were you proud of the work that you did at RJ Reynolds involving the inhalation studies and the product development work?
A Yes, I am.
Q Do you have any reservations whatsoever about the work that you did while you were at RJ Reynolds?
A None whatsoever.
MR. FURR: Dr. Coggins, it is nice to see you again, and please give my regards to your young family.

THE WITNESS: Thank you.
THE COURT: Mr. Westbrook, any recross?
MR. WESTBROOK: Yes, Your Honor. May I have a moment?
THE COURT: All right.
RECROSS-EXAMINATION
BY MR. WESTBROOK:
Q Doctor, just to close the loop on the Rodgman document about what was published and what was unpublished, Mr. Ohlemeyer said well, wasn't there reference by Dr. Rodgman about 12 papers were published. Those aren't the papers that Dr. Rodgman says

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concerns the cancer-causing substance, are they? He says -- do you have it, page 13, sir?
A Yes.
Q He says some of the findings have been published. That's the references Mr. Ohlemeyer referred to. And then he goes on, "However, much data remain unpublished because they're concerned with carcinogenic or co-carcinogenic compounds."
He is saying we published the ones that

didn't concern cancer causing, and we didn't publish the ones that concerned cancer causing. That's what he's saying in layman's terms, isn't he?
A I think that's what he's saying in this paper of '62, yes.
Q Now, the Witschi study, and Witschi's animals, Doctor, they all didn't get lung cancer in his study, did they? The controls didn't all get lung cancer? 80 percent of the exposed animals exposed to the smoke got cancer, 35 percent of the controls. That's a statistically significant difference. That's what you look for in science, isn't it?
A You used a word here that we haven't used so far and that's cancer. So far we were talking about tumors. Tumors may be benign or whether they may be malignant. When they become malignant, they are cancers. So far we've been talking about tumors and now you're starting to talk about cancers. There were very few cancers in this entire study. There was tumors. There were this bounce-back effect in tumors. I think it's

a very different situation when you look at cancers.
Q And you didn't find tumors in your rats.
A No, sir.
Q Now, you said Dr. Witschi exposed the animals all to extraordinarily high levels.
In the third study, the one you hadn't talked about on direct, didn't he filter the particulates down to the .1 level that you said was the level people are exposed to in buildings?
A I'm still not sure if it's .1, but certainly he introduced a filter called a high efficiency for particulates in air, the HEPA filter and, in theory, that should remove all particulates.
Q Now, Doctor, you talked about your apparatus for putting rats into the smoke in a tube. People don't breathe secondhand smoke in tubes, they go around in rooms and breathe it, don't they?
A They do, but I don't think they're going to lick themselves afterwards, which is what --

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Q They get it on their skin?
A I think that what we were trying to do --

and I'm not really trying to be facetious here -- was to make sure that we eliminated routes other than inhalation.
Q Do you think that oral ingestion of environmental tobacco smoke components can lead to tumors? You're talking about rats licking themselves, is that how they get tumors?
A Certainly the material that we were talking about very early on in the day, mouse skin painting, does produce tumors.
Q I'm not talking about mouse skin painting. I'm talking about the mice that lick themselves. Are they getting tumors from licking off the environmental tobacco smoke components?
A I don't know if they get tumors or not but they're getting material by a route that is not the same way that humans get it. I think that we were just trying to say we we're interested in inhalation and only in inhalations.
Q And to be clear, Doctor, no cigarette company sells reference cigarettes on the market, does it?

A No. The reference cigarette is designed to be a company industry average.
MR. WESTBROOK: Thank you, sir.
THE WITNESS: Thank you.
MR. OHLEMEYER: Very briefly, Your Honor.
MR. MOTLEY: We object.
MR. WESTBROOK: We object.
MR. OHLEMEYER: I'm sorry, excuse me.
THE COURT: Doctor, thank you for coming to Indiana.
THE WITNESS: Thank you, sir.
THE COURT: You are excused. You may step down. Have a good trip.
THE WITNESS: Thank you.
THE COURT: Call your next, Counselor.
MR. OHLEMEYER: Dr. Richard Carchman, Your Honor.
This way, Doctor.
THE COURT: Raise your right hand.
DEFENDANTS' WITNESS, RICHARD CARCHMAN, SWORN
THE COURT: Have a seat right there would you, please. Would you tell the jury

your name.
THE WITNESS: My name is Richard Carchman.
THE COURT: Would you spell the last name, please.

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THE WITNESS: C-A-R-C-H-M-A-N.
THE COURT: Thank you.
MR. OHLEMEYER: Doctor, you might have to slide that chair just a little forward.

DIRECT EXAMINATION

BY MR. OHLEMEYER:

Q Dr. Carchman, am I correct you are the vice president for scientific affairs, the R & D department at Philip Morris?

A Yes.

Q And how long have you had that position?

A Less than a year.

Q What was your position before that?

A I was group director of scientific affairs within R & D.

Q Tell us what your current job responsibilities are at Philip Morris.

A I oversee a group of scientists based in Richmond and around the world dealing in the

areas of environmental tobacco smoke and smoking and health in general.

Q And am I correct, Doctor, that you're also involved in general issues relating to smoking and health?

A That's correct.

Q This is not your first trip to Muncie, I understand.

A No. No. I came here, I guess, in the '80s when I was at the university and there was a meeting at Ball State, statistical meeting. And I also gave a lecture, a lecture there. I remember the coeds and the walnut trees and the weather was a little more pleasant than it is now.

Q Doctor, tell us about your educational background.

A I obtained my undergraduate degree in New York. I then worked for a while. It took me a bit of time to get my undergraduate degree because I was working full-time but once --

Q What was your degree in?

A It was in biology and chemistry with a minor in philosophy.

Q And while you were undergrad, did you work, did you say?

A Yes, I worked full-time. It took me about six years to finally get my bachelor's degree.

Q Where did you work?

A I worked at the U.S. Post Office, United Parcel Service, I worked bagging in a grocery store. I worked -- actually, ended up running a produce market at a supermarket finally at the end.

Q Did you do any work with Columbia University while you were there?

A Yeah. 1964 I took a job at the Institute

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for Cancer Research at Columbia university in New York, and I was there from 1964 to 1968 working in the laboratories of Dr. Eric Hershberg with joint work with Dr. Bernie Weinstein at the Cancer Center itself. And in '68 I left the Institute and went to the State University of New York, downstate Medical Center, for my doctorate degree in the Department of Pharmacology.

Q Let me back up for a minute. When you were at Columbia University, at the Institute for

Cancer Research, what sort of work were you doing? What sort of work were they doing and what were you doing?

A Dr. Hershberg's laboratory was involved in trying to understand and develop new drugs in the treatment of a variety of diseases, not simply cancer, and trying to understand, at the molecular level, how some of these potential drugs or drugs were working so as to try to improve their usefulness.

Q And what type of work did you do while you were there?

A I was in the laboratory basically full-time either carrying out experiments or designing and carrying out experiments. And some of that work was either presented at national scientific meetings or published in the peer-reviewed scientific literature.

Q Some of the work you were doing.

A Yes.

Q Now, was that considered basic research or a applied research?

A It was primarily basic, basic research.

Q Tell us what basic research is.

A Basic research, at least from where I came

from, with regard to my education and training, is trying to answer questions about issues that the facts aren't even available. You don't even know for sure what is out there, and you're sort of stepping into the unknown.

At that point in time what was known about cancer and certain diseases was much more primitive than is known today. But, still, there was a fair amount known. And to try to understand how a particular drug could specifically target a cancer cell and destroy it or a parasite and destroy it was part of what I was involved in. For drugs that apparently bound to DNA, which is an important molecule in the cell, and to figure out how it interacted with DNA and to try to make that drug better, to give it what was felt to be greater specificity. That is, that it would damage the harmful cell, whether it was a parasitic cell or a cancer cell, better than it would damage the normal cell was really the goal of this

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particular research.
Q And that would be basic research.

A That's right.
Q What is applied research?
A Applied research is something that you might find in the pharmaceutical industry where you have a menu of items available, whether it's a drug or a treatment, a vaccine, and you then set out and design a study to look at whether the drug works or the vaccine works, how it works, what side effects would be associated with it, whether it's something you can give to pregnant women, whether it has any differential effect based on ethnicity or some other kind of factor. But you're working -- you're working with something that you believe is going to work, and you're just trying to apply what was learned in the basic research field, excuse me, possibly in the clinical area.
Q And is that -- that process, taking basic research and applying it to products, something that occurs in any type of company that makes a product?
A I think that's probably a reasonable generalization.
Q Now, am I correct that then you went to the

State University of New York to get your Ph.D. degree?
A Yes.
Q And what was your area of study at State University of New York?
A It was in the department of pharmacology, and it was addressing a fundamental question of something that has turned out to be, continues to be a very large area of interest, and that is how do cells translate what happens from the outside to something on the inside.
So in the case -- in my thesis work, I was looking at a hormone that was made in the pituitary gland that affected the adrenal gland, which is found right above the kidney. And in this case we were looking at the adrenal gland making steroids. And my thesis work involved trying to understand the biochemical signals that transpired between the hormone coming to the cell and the production of the steroid.
Q And was that work published?
A Yes.

Q While you were doing your doctorate work, did you receive a fellowship from the National Institute of Health?
A Yes. I had an NIH predoctoral fellowship that paid me about $3,000 a year.

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Q Tell us what the National Institute of Health is.
A The National Institutes of Health are a group of institutes, primarily in Washington but not necessarily localized in Washington, that are part of really Health -- the Department of Health and Human Services, and it's probably the premier organization in the world in terms of basic research and in many areas of clinical research.
Q Was that a competitive grant?
A Yes.
Q What's the relationship between the National Institute of Health and the National Cancer Institute?
A The National Cancer Institute is one of the institutes within the NIH.
Q At any point in time during your education, up through and including your doctorate degree, did you get involved in the study of

molecular biology?
A The -- some of the work I did at Columbia, at the institute, looked at the molecular level in terms of how a particular kind of drug interacted with DNA. And that work was -- that work was published.
The work that I did for my doctorate was heavily -- heavily involved biochemistry, but not very much -- not very much at all at the molecular level. It wasn't until I went to do my post-doc that I got involved in molecular biology.
Q Tell us about your post-doc -- tell us what post-doctorate work is and what yours involved.
A Oftentimes when you finish your doctorate degree, you go on for additional -- additional training. When I was finishing up my degree, I had a couple of opportunities. One was at Yale to take my studies that I had done my doctorate with, take them a little bit further in Bill Douglas' lab and in Paul Gringard's lab.
And I actually had a real job offer at upstate Medical Center in Syracuse, in

Syracuse, New York, in the Department of Medicine and the Department of Pharmacology. And I made a decision that I wasn't going to go for a real job yet, because I didn't feel I had enough education. And I thought about what I wanted to do. And I wrote a letter to a scientist at the National Cancer Institute, Dr. --
Q Let me stop you there. Tell us what the National Cancer Institute is.
A It is the research body of the United States Government whose task and responsibility deals with trying to understand the causes of cancer and is involved in the prevention

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of cancer as well.
Q I interrupted you. Tell me about your work relating to that.
A Well, I borrowed somebody's car and drove to Washington and spent a day in Dr. Paston's lab, which was his office, which was probably no bigger than this little stand that I'm on. And we seemed to hit on all cylinders. And he said to me that if I wanted to come, he had no money. I would have to find my own money to come work for

him, and I had to let him know later that afternoon.

And this was the place for me to be. They were doing the kind of work I thought was very important in terms of advancing basic research and science, and so I told him that I would try to find a way to get some money and that I'd like very much to come work with him. So we shook hands and departed.

I went back to Brooklyn and finished writing some papers for my doctorate, and wrote a research application to the National Institutes of Health asking them to support my research in Dr. Paston's lab. And it turned out that I was fortunate. I got that award. They paid me $6,000 a year to go live -- go live in Washington for a number of years and work in his laboratory.
Q And how long were you there?
A I was there for almost -- almost two years.
Q And what was it exactly -- exact is probably not the right word. What was it that was being studied in that lab?
A There were two facets to the laboratory, and

I primarily focused in on the facet that dealt with the biochemical and genetic basis for cancer.

And that involved the study of some things that are called oncogenes. These are virally derived products that are found in cells that it turns out when they're modified in some way can produce -- can produce cancer. And I was studying some molecules that seemed to be important in the cell for not only preventing the cancer cells from progressing, but actually reversing it.
Q And how many labs or laboratories or people were studying that at that particular point in time?
A There were a number of laboratories around the world that were and continue to study those particular processes.
Q After you completed your post-doctorate work in molecular biology, did you then take a position teaching?
A Yeah. In 1974 I was offered a faculty

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position at the Medical College of Virginia in Richmond in the department of, at the

time, pharmacology.

Q And what is the Medical College of Virginia?

A It's part of the state system of the State of Virginia. There are -- at that point I believe there were only two medical schools that were operated by the State. One was at the University of Virginia in Charlottesville, and then the university -- the Medical School of Virginia, which is in Richmond, which is part of Virginia Commonwealth University.

Q So at this point in time you're not or weren't a medical doctor?

A No.

Q You had a Ph.D. degree?

A That's correct.

Q Is it common for Ph.D. people to teach medical students?

A It's not uncommon. The department I was in had a few physicians, but they were primarily Ph.D.s. If you looked at many of the basic science departments, and pharmacology is considered a basic science department, they're manned primarily, but not exclusively, by Ph.D.s who are involved

in teaching both medical students and dental students, as well as nurses and other allied health professionals some of the basic concepts and basic information they need to carry out their clinical responsibilities.

But I was also involved in teaching interns, residents and attendings. So these would be people who have already gotten their M.D. degree and are in the process of further advancement or training or education.

Q Did you do any research at the Medical College of Virginia separate and apart from your teaching?

A Yes, I did. In fact, the vast majority of my effort involved, at the medical school, involved research.

Q What type of research?

A It was basic -- basic fundamental research, trying to understand at the biochemical and molecular level some events that were going on in cells up to and including malignant cells. But not -- not solely focused on cancer, per se.

Q Did you obtain grants from organizations to

do that research?

A Yes, I did.

Q From who did you obtain grants? Tell us what a grant is to do research.

A Well, in the state of Virginia, though the

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State itself can provide some research funds, they're generally very limited. And so if you are going to carry out your own independent research, you have to apply for monies. And the sources of those monies include the federal government, and it could include the National Institutes of Health, within that the National Cancer Institute. It could involve other governmental agencies like the U.S. EPA, it could involve the FDA, could involve the Army. So there are a variety of government-related places to go and apply for funds.

There are also agencies, such as the American Cancer Society, the American Heart, American Lung. Those kinds of organizations also provide research monies.

And then you can, if you're doing something that has some applied function or use, if it's a pharmaceutical company, you

can get some research funds from those folks as well.

Q And I suspect with respect to the applied research, we've heard about funding from tobacco companies, pharmaceutical companies, automotive companies, anybody who has an interest in the research?

A That's correct.

Q Who was funding or who was sponsoring some of the research you did while you were at the Medical College of Virginia?

A All of the names that I've just gone through. Well, let me go through again specifically.

I had several grants over the years from the National Institutes of Health. I had some small grants from the American Cancer Society, the American Heart Association. I had -- was involved in some very large grants from the U.S. EPA, and I had a very large grant from the Department of Defense. There were probably some others that I had, but that's the general gist of where I got my research money from.

Q How long were you at the Medical College of

Virginia teaching?

A I came in the spring of '74, and I left in 1988.

Q Do you still have any appointment or any affiliation with the Medical College of Virginia?

A I have two affiliate appointments. I'm an affiliate professor in the Department of Pharmacology and Toxicology, and I'm an affiliate professor in the Department of Biostatistics.

Q Are you -- you have a Ph.D. in pharmacology; right?

A Yes.

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Q And do you have background and training in toxicology?
A Yes.
Q How did you obtain your training in toxicology?
A Well, in the process of doing pharmacology, you are inevitably drawn into the study and examination of toxicological principles. And I ended up teaching in those areas in the department and to graduate students in the areas of general toxicology,

cardiotoxicology, genetic toxicology.

I'm also a member of two of the premier toxicology societies in the United States. The Society of Toxicology and the American College of Toxicology. And I have been involved in putting together symposia for some of these professional societies in these kinds of areas.

So basically through self -- self-training, education, educational experience, research experience is how I came to fall into toxicology.

Q Are you familiar with something known as the Massey, M-A-S-S-E-Y, Cancer Center?
A Yes. The Massey Cancer Center is, at least when I was there, it was one of the National Cancer Institute's funded cancer centers in the United States.
Q And what was your association with it or involvement with that organization?
A Dr. David Goldman was the director of the Massey Cancer Center, and I was the associate scientific director of that center.
Q For how long?

A Oh, for a couple of years, I think.
Q And what were your responsibilities as associate scientific director?
A One was to make sure that the research that was carried out at the university, per se, that could relate to or did relate to cancer research had an opportunity to gain access to the advanced technologies that the center had.

And to try to make sure that collaborations with folks around the world who were doing research that touched upon these activities also were involved.

So it was an attempt to bring research both at the university and other universities and other places around the world together where it made sense from a research perspective.

Q In connection with your research, have you published any articles in peer-reviewed journals?
A Yes, I have.
Q Can you tell me whether you've published any

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chapters in scientific books or textbooks?
A I think I've published 12 or 13 chapters.

Q How many articles have you published?
A In peer-reviewed journals?
Q Right.
A 80 or 90 articles.
Q And in general what topics or what are the issues or topics upon which you publish?
A In general it has to do with biochemistry and understanding of cell -- cell function in normal cells and in diseased cells as well.
Q And, Doctor, have you served as a reviewer for any scientific publications or journals?
A While I was at the university, I served as a reviewer for a number of scientific journals in the areas of pharmacology, toxicology, and immunology.
Q What does it mean to be a reviewer for a journal?
A It means different things to different people, I guess, but in general when you submit an article for consideration in a peer review journal, it goes to an editor. The editor looks at the article and says, well, does this or does this not fit into the mission of the journal.

If it fits into the mission of the journal, the editor then says who out there might be a good person with expertise and knowledge in this area to review this in an objective but yet critical manner. And so the editor then decides who that goes to and sends those articles out to be reviewed. They could go to as many as two or three outside reviewers for critique.

But, basically, it's the knowledge of the editor that an individual has published in this area, is viewed as an expert in this area that gets them to be involved as a reviewer for such kinds of articles.
Q And have you served as a reviewer for the Journal of Immunology?
A Again, while I was at the university, from time to time I would get articles to review.
Q Have you reviewed articles for the Journal of the American Society of Pharmacology and Toxicology?
A Yes.
Q What about the journal known as Cancer Research?
A Yes.

Q What is the journal Cancer Research? Who publishes that?
A The Journal of Cancer Research is one of the major journals of the American Association of Cancer Research, of which I've been a

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member for 10, 15 years. It is one of the premier cancer research journals, both in terms of basic research and some aspects of applied research.

Q Have you served as a reviewer for the Centers of Disease Control or the National Institutes of Health?

A Yes.

Q Tell us what the Centers for Disease Control is.

A The Centers for Disease Control and Prevention in part dealt with an issue that seems to have resurfaced itself in the United States these days, and it has to do with the disposal of chemical warfare and biological warfare agents. And there was an effort to try to dispose of these materials, oh, more than 15 years ago, and I was involved in an attempt to find a way to do that. But there was a lot of public concern

about the safety associated with this. And nothing really happened.

And again, today, if you read the newspapers, it's sort of resurfaced, as I said, again as a hot issue.

Q Have you have you ever served on any review committees for the Environmental Protection Agency?

A Yes, I have.

Q Describe that work for us.

A Well, I actually both served as a reviewer and I was a consultant for a number of years as it related to the Clean Drinking Water Act.

The EPA was sued, I think, by the National Research Defense Council for not having acted as quickly as they felt they needed to act on what are called priority chemicals in drinking water.

Most times the United States -- the drinking water that we all consume here is chlorinated water. And when you add chlorine or chlorine derivatives to water, you end up creating hundreds, if not thousands of chemicals in the drinking

water. And EPA was charged with the responsibility of assessing the safety of this water.

And I was asked, with a number of other folks in the United States, to sit down and help the Agency in terms of their scientific deliberations with regard to drinking water as an example.

Q Are you familiar with the process by which the EPA conducts risk assessments?

A Yes, I am.

Q Are you also familiar with the process by which the EPA considered its risk assessment relating to environmental tobacco smoke?

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A Yes, I am.
Q In general, Dr. Carchman, how did the process by which the EPA conducted its risk assessment with respect to environmental tobacco smoke compare to the process by which it conducts risk assessments for other substances?
A Well, I can't speak for every other substance the EPA has done a risk assessment on, but the ones that I'm familiar with, when it comes to environmental tobacco

smoke, for my view, is that it was sort of like the fellow who shot an arrow into a wall, went over and drew a circle around it and said bull's eye. And that's based primarily on a couple of facts.

When you do a risk assessment, you're asking yourself --

MR. MOTLEY: Excuse me, Your Honor, if the gentleman is going to offer opinions, I request that he be instructed to offer them to the requisite degree required by the law of Indiana, and not just sit here and offer facts without me knowing whether or not opinions -- without me knowing whether or not it's based on a requisite degree of certainty that's required. That question is not forthcoming yet from Counsel.

He may intend to ask it at the end of the inquiry, but at this point in time I don't know whether he is now guessing, speculating, giving possibilities, what he's doing. I think I'm entitled to know. If not, then I need to voir dire him on that issue.

MR. OHLEMEYER: What I've asked the

witness, Your Honor, what I'll ask him again is to compare, based on his observations and participation in risk assessments, the process by which the EPA conducted the ETS risk assessment compared to the ones he's familiar with.

MR. MOTLEY: I have no problem with that. My problem now comes when he is -- without being elicited he is now giving us opinions. And it's difficult for me sitting over here to discern the difference between what he is observing factually and what he's stating scientifically. And I just think that the witness needs to be cautioned at the start that there is a distinction between observed facts and opinions that are offered by an expert witness, and I don't know that he's ever been. He may have been. I don't know if he's ever been in a court of law in a civil case or not but I think that we're entitled to know the opinions he's giving, whether they have the requisite foundation to be allowed the trustworthiness

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that would allow Your Honor to let the jury consider them.

MR. OHLEMEYER: Your Honor, with all due respect to Mr. Motley, there are opinions that lay witnesses can make based upon their perception of things under Rule 701. Then there are opinions that witnesses specifically retained to offer opinions about based upon information provided to them. I think this question doesn't call for the type of opinion Mr. Motley is inquiring.

This question calls for a comparison based on this witness' observations and his knowledge of the ETS risk assessment and the risk assessment he was involved in.

MR. MOTLEY: Your Honor, one need look no further than the chart Dr. Levy showed us to understand that this is not a matter about which there is a great deal of knowledge, at least on my part as a layperson with respect to epidemiology.

Now, I'm not trying to obstruct anything here. I just think we need to delineate so I'll know which are things that he's claiming to be observed fact and which are things he's claiming as an expert,

because he's listed as an expert.

And if he's going to ask him a lay opinion, he ought to do that so, in fairness, Your Honor, I have an opportunity to understand what's going on here.

THE COURT: All right. Thank you, Counselor. The last question was a fair question. The objection is overruled. Mr. Motley will have an opportunity to cross-examine this witness on his opinions.

Go ahead, Mr. Ohlemeyer.

Q Do you recall the question, Doctor?

A Yes, I did. And I was about to give a scientific explanation for the answer.

Q Well, what I want you -- maybe I'm not making myself clear. What I want you to do is you're familiar with the process by which the EPA conducted its ETS risk assessment.

A Yes, I am.

Q You've reviewed their materials, including their methods and their data.

A That's correct.

Q And you're familiar in some measure with the process by which they've conducted other risk assessments.

A Yes, I am.

Q What I want you to do is compare for me the process, how did the process -- how were they similar and how were they different?

A The major difference was that in their risk

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assessment, they had already concluded that there was a risk. And what their risk assessment came down to was how large a risk there was. And the basis for my statement is they used a one-tailed T test.

Q Which is what?

A A one-tailed T test asks the question how big is the risk. The normal risk assessment is a two tail that basically says is there or is there not a risk.

So as soon as you go to a one-tail test, you're no longer asking yourself the question is there a risk. You're asking how big is the risk.

And they also used a 90 percent confidence interval to capture that from a public health policy perspective. That's a very conservative way of estimating it. They're trying to protect the largest number of people, in this case in the United

States, against something that they have defined as a risk.

That's the basis for my statement that they have already determined that it wasn't -- that it was a risk and they were just trying to determine the size -- the size of that risk.

Q In the other risk assessments they conducted with which you're familiar, did they use a 90 or 95 percent confidence interval?

A Generally speaking 95 percent confidence intervals are what are used, and those are determined before you do the risk assessment.

In the case of the EPA, they changed somewhere downstream from using the 95 percent confidence interval to a 90 percent, which is a broader, not as restrictive, not as rigorous in a statistical sense.

There is nothing wrong with a 90 percent or a 95, as long as you determine in the beginning what it is you're going to do. It is a violation of scientific principle, whether it's in statistics or in normal experimental design, to change what you're

doing in the course of your examination.

Q And is that consistent or inconsistent with what they did in other risk assessments with which you're familiar?

A That's inconsistent.

Q Now, in connection with your work, either while you were in school or postgraduate, did you receive any other awards or any other fellowships to further your research?

A While I was at the university, I applied for and won a Research Career Development Award from the National Institutes of Health. I think at the time it was from what was the diabetes, the Diabetes Institute. And that

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enabled me to spend five years focusing on my research and minimizing my administrative responsibilities. I was the first faculty member in the department to win such an award.

Q Did you receive any sort of awards or fellowships from the United States Environmental Protection Agency?

A For the work that I did for the EPA in their toxicology and risk assessment of the priority chemicals in drinking water, I got

a little plaque of recognition from Dr. Jerry Star, the late Dr. Jerry Star, who was the scientist at EPA who was in charge of this entire effort.

Q Am I correct you started working at Philip Morris in about December of 1988?

A Yes.

Q Tell me how that came about.

A Over the years at the medical school, I had an opportunity to train a wide variety of people from around the world, people trying to get their doctorate degree, physicians from various parts of the world who wanted some advanced -- some advanced training, even some physicians that wanted to get their Ph.D. degree, and some veterinarians, people with DVMs, veterinarian degrees.

And one day in my office, a colleague of mine came in with a potential candidate, and this potential candidate, whose name is Jim Charles, was an employee at Philip Morris in R & D. And he asked me if I would sit and talk to him.

So I spent a couple of hours talking with Jim Charles about where he wanted to

go, why he wanted to do this. And at the end of the day, I encouraged him to apply to the graduate program. He applied. He got in. He took all of the courses that were required of him. And the only precondition that I set for Jim was that he submit for publication to peer-reviewed journals the efforts of the work in my laboratory.

And so Jim was an outstanding student in the classroom. Probably if I would have had more students like him, I would probably still be at the university. He was just one of these fellows who just didn't go home. And he did everything he said he was going to do, and his work was published in the peer-reviewed literature. He went back to Philip Morris.

And we would have lunch, oh, once a month, once every other month. One month I would pay for lunch, one month he would pay for lunch. We developed, I guess, a friendship. And this went on for a number of years.

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And I want to say in '85 or '86, Jim had gotten his degree. He called me and he

asked me if I would be willing to consult for Philip Morris in the area of toxicology. And I said, Well, let's sit and talk about this. We talked, and I said yeah, I would be willing to do some consulting for you. And I did some, very small amount of consulting, in a very particular question.

And then in 1988, Jim came to me and asked me if I would come to work for him at Philip Morris. And I said, Jim, I said, I own one tie. It goes with everything I possibly can wear. I don't know if I would fit into a non-university environment.

But I went down there. I spoke with his boss, Dr. Ken Howton. I went back and I spoke to my chairman. And I said, can I take a sabbatical; that is, can I leave the university for a year? See what it's like working in a big company. And if I don't like the big company, or they don't like me, I can come back. I have my students, my research was actively going on. I had very large research activity in a number of different areas.

And so after consultation with my wife,

I took a sabbatical from the university for a year. At the end of that year, I tendered my resignation at the university and became a full-time employee of Philip Morris R & D.

Q And that was December of '88.

A Yes.

Q When you did the consulting on the toxicology issue, what was the issue you were consulting on?

A Ingredients.

Q What are ingredients?

A There was a federal law passed, a Federal Cigarette Labeling and Advertising Act, abbreviated FCLAA, that required the U.S. industry to submit a list of the ingredients added to tobacco in the manufacture of cigarettes to the Department of Health and Human Services, specifically to the Office of Smoking and Health.

And in '86, 1986, the first list was submitted to the federal government as it relates to that particular law. And I was involved at that time in looking at the list of ingredients that Philip Morris was going to contribute to this U.S. industry list.

Q At that time were there other regulations in other parts of the world that related to these types of things?

A For a number of years, there have been regulations regarding what you can put into

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a cigarette. In fact, the very nature of the cigarette construction in Germany, in France, in the United Kingdom, that was at that particular -- at that particular time.

Q So when you started in December of 1988, you had more or less been at the Medical College of Virginia or in other research activities since you had left college?

A That's correct.

Q Did you have any reservations about going to work for a tobacco company?

A Well, that was what my first year was really -- was really about. And there was some things that really convinced me to stay. One was I was hired as a technical person. And the technical individuals that I interacted with were of a very high caliber and standard. And I got to meet some Philip Morris scientists, not just in Richmond, but in other parts of the Philip

Morris R & D-related community.

And at a facility, research facility that Philip Morris has in Europe, I met some scientists of the highest technical character I have ever met anywhere in the world. And I looked and I studied for a significant amount of time what they were doing and how they were doing it. And it was one of the things that convinced me that the company was very serious about the efforts that it was involved in, and it helped convince me to stay, to leave the university and stay with Philip Morris.

Q At the point in time where you joined Philip Morris, were they manufacturing and selling cigarettes in other parts of the world?

A Yes.

Q Did they have facilities and employees in other parts of the world?

A Yes.

Q And did those parts of the organization interact on a routine or regular basis?

A Yes.

Q What was your first position at Philip Morris?

A I was hired as a principal scientist.

Q And what is a principal scientist?

A It's the highest technical position within the R & D organization.

Q Is it A-L or L-E?

MR. WAGNER: A-L.

A A-L, thank you.

Q How long were you a principal scientist?

A About a year and a half.

Q And what were your responsibilities during that period of time?

A The main focus of my responsibilities had to do with ingredients.

Q And were you involved with something called

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INBIFO, I-N-B-I-F-O, at that time?
A Yes, that was the research facility in Europe that I was referring to. That's the acronym for it.
Q What does it stand for?
A In English it's the Institute for Biological Research. It's a German acronym, but in English it just means the Institute for Biological Research.
Q And then what was your next position at Philip Morris?

A Well, I was asked to become manager of biochemical research, and I basically said I did not come to Philip Morris to be a manager. I came to do technical things, and they told me that this would be a responsibility that I would have in addition to my technical responsibilities, and it would last for no more than two years.
Q And what responsibilities did you have? What were you managing as the manager of biochemical research?
A There was a group of 50 scientists in Richmond, in the R & D facility, that carry out a variety of both research and applied activities in support of both the business and regulatory-type issues.
Q How many -- at the time you got to Philip Morris, how many people or how many scientists were employed -- I guess we ought to define what I mean by scientists, but how many scientists, and how would you define scientists, were employed in the research and development department?
A In Richmond, there were something close to 600 people in R & D. Over 100 were Ph.D.s.

Q People with doctorate degrees?
A Yes.
Q And when you got to Philip Morris, did they have the appropriate facilities to do the kind of research that you thought you were going to do?
A They either had them in Richmond or they had them in Europe, but whatever was needed was available.
Q And after your time as manager of biochemical research, what was your next position?
A I became the director of scientific affairs.
Q And what were your responsibilities as director of scientific affairs?
A In addition to ingredient-related matters, I then had the additional responsibility of environmental tobacco smoke scientific issues.
Q Are you the chief scientist at Philip Morris on ETS matters?
A Yes.
Q What do your responsibilities include with

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respect to ETS?
A Within Philip Morris, we have had, and

continue to have, research activities that involve investigations into the chemistry and physical nature of what is or might be environmental tobacco smoke. We have ongoing research of a biological kind, primarily in Europe, that has been, for the last 15 years, been investigating or trying to understand various aspects of environmental tobacco smoke. That's within the company.

Outside of the company, my major area of responsibility is as a member of the board of directors of the Center for Indoor Air Research, which is an organization started in the spring of 1988, so it started before I came to the company.

And the main responsibility of that organization was to investigate and support research in the areas of indoor air quality, including environmental tobacco smoke. It was -- the organization was started initially with Philip Morris, RJ Reynolds, and Lorillard Tobacco at that point in time. It has grown over the years.

Its primary support still comes from --

still comes from the tobacco industry. But it is probably the largest single non-governmental body that supports research in the area of indoor air quality and ETS in the world.

Q Does the fact that tobacco companies provide money and resources to this organization make it a front organization for the tobacco industry?

A I think that's the view of some people, but the people who either receive money from -- from the center, or the people who serve as reviewers for proposals from the center, or the people who serve on the outside Scientific Advisory Board, I think, don't feel that way -- don't feel that way at all.

Q Doctor, let me hand you what I've marked as Defendants' Exhibit CA1.

MR. OHLEMEYER: Your Honor, I'd move CA1 into evidence.

MR. MOTLEY: It is already in evidence as part of the document of Mr. Westbrook, but I have no objection.

MR. OHLEMEYER: It's not in evidence, Your Honor.

MR. MOTLEY: It's P93, Your Honor. It's attached to the document -- excuse me.

MR. OHLEMEYER: I'm trying to clear something up, Your Honor. Mr. Motley is mistaken.

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THE COURT: One at a time.
MR. MOTLEY: I'm glad for it to come back in. It doesn't matter to me.
THE COURT: Mr. Ohlemeyer.

BY MR. OHLEMEYER:

Q Dr. Carchman, let me hand you a copy of the 1988 research agenda for the Center for Indoor Air Research.

A 1998.

Q '98, I'm sorry.

MR. MOTLEY: Excuse me. You said agenda something?

MR. OHLEMEYER: I handed him the book from which this page came.

MR. MOTLEY: I was talking about this page.

Q Turn to the front cover there. Is Exhibit CA1 a copy of that front cover?

A Yes.

MR. OHLEMEYER: For the record,

Your Honor --

Q And this is the 1998?

A Yes.

MR. OHLEMEYER: For the record, Your Honor, Plaintiffs' Exhibit 2815 is a 1994 version of this document.

THE COURT: Thank you, Counselor. Any objection to CA1?

MR. MOTLEY: None, Your Honor.

THE COURT: CA1 will be admitted.

(Defendants' Exhibit(s) CA1 received in evidence.)

Q I've blown this page up, Dr. Carchman, and I want to ask you some questions about it.

May I have this? Is this, this research agenda that we've referred to, something that's published by the Center for Indoor Air Research?

A Yes.

Q Is it publicly available?

A Yes.

Q And does it contain a statement of the Center's mission?

A Yes, it does.

Q Tell us what the mission of the Center for

Indoor Air Research is.

A To sponsor high-quality research on indoor air issues and facilitate communication of research findings to the broad scientific community. And by communication, what this really is about is submitting the research that the Center sponsors to peer-reviewed journals for their consideration.

Q When you say "sponsor," how does the organization sponsor it?

A In that brochure that you have there, Mr. Ohlemeyer, I believe there is some information on how to apply for monies from the Center. And it also outlines the areas

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of research that the Center is interested in sponsoring. And those areas are established by the members of the Scientific Advisory Board, which are listed on this board that you have up here.

Q Where does the money come from to sponsor that research?

A It comes from dues of the members.

Q And are there members -- do the members include Philip Morris, RJ Reynolds, Lorillard, Brown & Williamson?

A That's correct.

Q Hoechst Celanese?

A Yes.

Q Who is Hoechst Celanese?

A They're a major manufacturer of paper products, for example.

Q And do they make cigarette paper or cigarette filters?

A Yes.

Q There are some associate members. What are they?

A The associate members are people who have an interest either in the area of indoor air quality and/or in -- they also could be vendors, people that the industry does business with. But they could also, I think -- I haven't seen -- if you can just show that to me, I might be able to be a little bit more helpful.

The associate members here are all people who were involved as vendors to one or more members of the industry.

Q And you are the chairman of the board of directors of this organization?

A That's correct.

Q What's the difference between the board of directors and the Scientific Advisory Board members?

A The Scientific Advisory Board sets the overall research agenda for the Center when the applications come in, and we've been averaging, I want to say roughly maybe 80 applications a year, they go to the individuals listed here.

Dr. Max Eisenberg is the executive director of the Center, and so he sits down with the members of the SAB, and based upon their expertise they divide up these 80 research proposals that come in.

Once these proposals are then divvied up, they are then distributed to a number of reviewers all over the world. And these reviewers can be university people, they can be individuals from other industries, they can be governmental scientists, whether it's the EPA or some other governmental agency.

And so each proposal is reviewed at least by a member of the SAB, and oftentimes

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three or more outside reviewers. Those reviews come back in to the Scientific

Advisory Board. They sit for several days and review all of this and they then vote.

Based on that vote, they then prioritize as to whether a proposal is acceptable or not. And if it is acceptable, they prioritize within the level of acceptability.

So those which are acceptable then come to the Board of Directors, which are made up of members of -- two members each from Philip Morris, from Reynolds, from Lorillard, and B&W. And they're all scientists. They're either chemists, physicists, toxicologists, but they're all scientists.

And we then spend several days going over the prioritized list that the SAB has approved, and we have a stack of money on the left, and we have proposals on the right. And we just go down the proposals until the money -- the money runs out.

And generally speaking, we fund 15 to 20 of the approved proposals that the SAB passes on to us.

And this is handled in a contractual

way, where there are responsibilities of the investigator. They have to fulfill certain submissions of information to receive their money. And the only thing that they're encouraged to do besides fulfilling those responsibilities, and it's listed in this booklet, is to acknowledge support from the Center, and they're encouraged to publish their findings.

Q Is this the way other types of organizations fund or sponsor research?

A Actually, again in here, Dr. Eisenberg acknowledges the help of the Health Effects Institute, whose application format is really what we use at the Center.

The basic --

Q I'm sorry to interrupt. Go ahead.

A The basic function that I've just described here is very common to what goes on in any kind of research evaluation, whether it's done by the federal government or some other funding agency.

Q And with respect to these reviewers, the reviewers are people who the proposals are sent to to critique?

A Yes.

Q Am I correct that there's a list of who these people are, and that some of them are affiliated with universities, some of them are actually affiliated with the United

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States EPA; is that right?
A Yes.
Q The Harvard School of Public Health?
A Yes.
Q Different private industry?
A Yes.
Q The National Institute of Standards and Technology?
A Yes.
Q Let me ask you to assume, Dr. Carchman, that the jury has seen evidence that the 1994 Scientific Advisory Board members of the Center for Indoor Air Research were William S. Cain, Michael R. Guerin, Irving Kessler, Morton Lippmann, Genevieve M. Matanoski, Demetrios Moschandreas, Mark Utell, Alfred Wolf, and James Woods.
If that were the case, is it fair to say that the exact same people are on the Scientific Advisory Board who were on the

Scientific Advisory Board in 1994?
A That's correct.
Q And am I correct that these are not individuals who work for tobacco companies?
A Hardly.
Q Tell us who Morton Lippmann is.
A Dr. Lippmann actually was the chairman of the EPA's ETS risk assessment.
Q Tell us who James Woods is.
A James Woods is an engineer, an expert in ventilation/filtration technologist. He, too, served on the EPA's ETS risk assessment.
Q Dr. Carchman, is there any other organization in 1998 that sponsors as much research in this area as the Center for Indoor Air Research?
A There could be parts of the EPA that do, but I'm not sure. It's pretty close in terms of actual dollars being funded.
Q Now, I realize it's not your responsibility to Philip Morris, but are you aware of the fact that Philip Morris spends a considerable amount of money each year on advertising for its products?

A I'm generally aware of that.
Q Do they spend as much money sponsoring this type of research as they do on advertising?
A No.
Q Why not?
A Well, the fact that you have a lot of money to do research is always -- is always helpful. Advancements that are made in research clearly do require money to move forward. But to move knowledge forward, information forward, you also have to have technologies available to do that. And in the absence of having the right techniques and the right kinds of technologies, you

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become wasteful and you basically end up throwing the money -- throwing the money away.

So just having money is clearly important, but having the technologies and the understanding to be able to utilize them has to be somehow coupled with having the necessary money to do the work.

Q And in your opinion, is this organization and your company doing that?

A Yes.

MR. MOTLEY: Excuse me, Your Honor. There we go. I did hear the word "opinion." I don't know if he's asking him a lay opinion, an expert opinion.

THE COURT: I'm not sure I understood his answer. Are you asking him, Counselor, why didn't --

MR. OHLEMEYER: My question --

THE COURT: Don't interrupt me.

MR. OHLEMEYER: I'm sorry.

THE COURT: You asked him did they spend as much money on research as they did on advertising?

What was your answer?

THE WITNESS: My answer was that they probably spend more money on advertising.

THE COURT: And I think you asked him why?

And what was your answer to that?

THE WITNESS: My answer was that having money was important, but having the technology and the information to be able to couple them together was also critically important. Otherwise, you were just

throwing money away.

THE COURT: Okay.

MR. OHLEMEYER: And then my next question, Your Honor, is as the director of scientific affairs, has the company and this organization coupled the technology and money in an appropriate way.

MR. MOTLEY: I heard the word "opinion," and I didn't know -- that's the reason I stood up, because I thought Your Honor invited me to wait and listen, and when he got into opinions I could stand up again.

THE COURT: The last is a fair question.

MR. MOTLEY: Can I hear the question back, Your Honor, please?

THE COURT: All right. Would you tell us the last question Mr. Ohlemeyer posed.

(Off the record discussion.)

THE COURT: Did you understand the last question, Doctor?

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THE WITNESS: Yes, I did.
THE COURT: You may answer the last

question.
A The last question basically wanted to know if the amount of money we were spending given the current state of knowledge and technology was appropriate.
Q Correct.
A And my answer is yes.
Q Doctor, let me ask you a couple questions about INBIFO.
MR. OHLEMEYER: Your Honor, I'm changing topics, do you want to --
THE COURT: I think we'll take a break at this point. Pass the exhibits down, if you would, ladies and gentlemen. We will break for 15 minutes.
Doctor, you may step down.
MR. CASSELL: All rise.
(A brief recess was taken.)
MR. CASSELL: All rise.
THE COURT: Be seated. All right. Jury back in its entirety.
MR. OHLEMEYER: Your Honor, is your preference that the witness be in the box when we start?
THE COURT: That's sometimes

difficult to do. This is fine.
MR. OHLEMEYER: Doctor, you'll need to state your name again for the record.
THE WITNESS: Richard Carchman.
THE COURT: Thank you.
MR. OHLEMEYER: Thank you, Judge.
Q Doctor, let me ask you about this -- you mentioned INBIFO, I-N-B-I-F-O. Tell us again what that is and where it's located.
A It is a center for biological research for Philip Morris, and it's primarily located in Cologne, Germany.
Q And who owns it?
A Philip Morris.
Q How long has Philip Morris owned it?
A 25 years, plus or minus.
Q Do you know why that facility is in Europe as opposed to Richmond?
A I have some indication that it was the fact that they were looking for a facility to do biological research. And in terms of their investigations, there was such an institute in Cologne, Germany.
MR. MOTLEY: Excuse me, Your Honor. I hesitated to stand up and interrupt, but I

believe you just said it occurred 25 years ago. I have no objection if he's testifying about documents that he's looked at but I think that ought to be clear on the record.
MR. OHLEMEYER: Well, let me

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rephrase it. I'll withdraw the question and rephrase it.

THE COURT: All right.

Q You've been involved with INBIFO since the time you became a principal scientist at the company?

A That's correct.

Q Have you actually been to INBIFO?

A Numerous times.

Q Have you worked with the people at INBIFO?

A Yes. In fact, I had for a number of years day-to-day responsibility for interfacing between INBIFO in Europe and the rest of the company.

Q And is it your understanding that the facility was in existence before Philip Morris acquired it?

A Yes.

Q Who owned it before Philip Morris bought it?

A I don't know.

Q Is the existence of that facility a secret?

A Possibly to some -- some people. Generally speaking -- I don't consider it a secret, if I could explain.

Q Well, let me ask you this, Doctor: Have representatives of government agencies visited that facility?

A Yeah. The Food and Drug Administration has been there.

Q And what goes on there?

A A number of things. One, we currently have, to my knowledge, the only lifetime ETS animal inhalation study ongoing, so there is a fair amount of work related to evaluations of environmental tobacco smoke in biological systems.

There's product development and evaluation work. It's the place where, if ingredient questions arise that require biological testing, that's where that testing is done.

So those are the kinds of things that go on there.

Q And is that facility used by Philip Morris companies throughout the world?

A It's primarily used by Philip Morris U.S.A., although Philip Morris-Europe has over the years also used that facility.

Q Dr. Carchman, I want to talk now about environmental tobacco smoke and research that Philip Morris has conducted in that area.

Can you tell us how long Philip Morris has been doing research on the issue of environmental tobacco smoke?

A The effort that continues to go on, I guess started around '82, '83, something in that time frame.

Q And in connection with your work as director

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of scientific affairs, were you required to become familiar with that work?
A Yes, I was.
Q Why didn't that type of work -- strike that.
Could that type of work that began at that point in time have been done sooner?
MR. MOTLEY: Excuse me, Your Honor. I just need to know if he's talking about -- is he asking him his opinion as a scientist, is he asking him if he's reviewed documents and come to a conclusion or is he asking him

did he observe something? He didn't get there at the time. He wasn't there in 1982. I'm not objecting. I just would like to know the basis for the answer, that's all.
THE COURT: You mean, Counselor, in his capacity as a scientist for Philip Morris whether or not they could have begun the studies earlier?
MR. MOTLEY: I want to know if he's offering an opinion as a scientist, if he's offering a observation of some --
THE COURT: Make your question a little more clear.
MR. OHLEMEYER: Absolutely, Your Honor.
Q Dr. Carchman, what type of research did Philip Morris begin in the area of ETS when that research began?
A It was to try to understand the chemical and physical nature of what people were calling environmental tobacco smoke or passive smoke.
Q And what does that mean, the chemical or physical nature?
A In one sense, when you go into a room in

which people are smoking, you can either visually observe smoke or smell smoke, and this was viewed by some people as being environmental tobacco smoke.
If you want to understand this as a scientist, you have to define the parameters of the study. You have to know what it is you're going to be testing. And that turned out to be a very, very difficult task because, as you can imagine, whatever environmental tobacco smoke is can vary as a function of the location, the number of people smoking, the ventilation, filtration, et cetera, et cetera.
So if you want to do this in a scientific manner, you have to try to understand some of the fundamental characteristics of whatever ETS is.
Q And is that the process that began 10 or 15 years ago by Philip Morris?
A Yes.
Q Why couldn't that process, based on what you know about the issues, and based on your

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experience as a scientist, and based on what you know about analytical techniques, is

that a process that could have begun sooner than 10 or 15 years ago?

MR. MOTLEY: Again, Your Honor, he's using the word "could." If he's offering an opinion, I don't think that's a requisite foundation for it. I just wish he would clarify. I don't mean to keep interrupting but I need to know if he's offering an opinion. He's listed as a scientist and an expert witness and a fact witness, so I just would appreciate knowing where we're going with this because, if he's offering an opinion now, "could" is not sufficient. I've gotten cases here that support what I'm arguing about, Your Honor, if you'd like.

THE COURT: The objection is overruled. It's a fair question.

Repeat your question.

Q Do you recall the question, Dr. Carchman?

A Could you repeat it, please?

Q Yes. Based on what you know about analytical techniques, and based on what you know about the chemistry and physical nature of environmental tobacco smoke, and based

upon what you know about the work that began at Philip Morris 10 or 15 years ago to determine the chemical and physical nature of that substance, my question to you is, Is that the kind of work or research that could have been conducted at an earlier point in time?

MR. MOTLEY: Objection, Your Honor, my objection is that calls for scientific opinion, that it's not the requisite degree of probability required under the case of Noblesville Casting Division of TRW, Indiana Supreme Court, vs. Prince. "Could" means possibly, and if this is an expert opinion, that's not sufficient under Indiana law and I object.

MR. OHLEMEYER: I'll rephrase the question.

THE COURT: Overruled. You may answer.

MR. OHLEMEYER: You can answer that question now.

A Can we try the question one more time?

Q I think so.

MR. MOTLEY: I won't object this

time.

Q Based upon your background, your education, your experience, based upon what you have learned and come to know in research with respect to environmental tobacco smoke

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during your years at Philip Morris, based upon your review of the research at Philip Morris in this area that was conducted before you got there, based upon what you know about analytical and chemical techniques to measure the chemical and physical nature of environmental tobacco smoke, is the type of work that began at Philip Morris 10 to 15 years ago in this area the type of research that could have been conducted at an earlier point in time?

A For some of the materials that are found in environmental tobacco smoke, the answer is probably yes. But for many of the others, in fact, many of the ones that are considered to be important from a health perspective, the answer is probably -- probably not.

Q Why not?

A Because what environmental tobacco smoke is,

it is diluted tobacco smoke from any number of sources, and diluted to such an extent that whatever chemicals might be there are found in vanishingly small levels.

And so though there are analytical techniques, as I said, for measuring some of these materials, it's not a simple task to measure very, very small amounts of some of these -- some of these materials.

And there is some potential examples I could give if anybody was interested.

Q Tell me what you mean by that. Give me an example.

A Well, if you look in, say, some of the government reports on sidestream smoke, which is the smoke that comes off the end of the cigarette between puffs, that is viewed to be a contributor to environmental tobacco smoke.

Q Let me stop you for just a moment. Tell us what the difference is, if any, between sidestream smoke, mainstream smoke, and environmental tobacco smoke. Briefly. We've heard a little bit about it, but tell me what your understanding of these three

things are.

A The common thread is they're all derived from burning tobacco.

Mainstream smoke is that smoke which the smoker inhales when puffing on the cigarette.

Sidestream smoke is the smoke that comes off the end of the cigarette between the puffs.

And environmental tobacco smoke is composed of whatever exhaled smoke comes from a smoker and the diluted sidestream smoke that's coming off the end of the cigarette between puffs.

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Q At what point does sidestream smoke become environmental tobacco smoke?
A That's a very good question. And it's one that we and other people have been investigating for a long time. Dilution in this room, if I were smoking, smoking a cigarette, the smoke both that I exhaled and the smoke that would come off the end of a cigarette would be diluted into this space. This is a pretty good size space.
You also have time. From zero time,

from the time I take a puff and let that cigarette burn, to the time it gets diluted. During this time and during the dilution, things happen. Things happen from a chemistry perspective and things happen from a physics perspective with regard to the materials in the smoke.
Q So is there such a thing as sidestream smoke, per se? At what point am I being exposed to sidestream smoke as opposed to environmental tobacco smoke if I'm in a room where you're smoking?
A We and other people have, as I said, investigated this area. And if you look at publications or research in this, they describe fresh sidestream. That's sidestream that comes right off the cigarette that you evaluate at that moment in time.
Then there is something called aged sidestream, which gets you closer to environmental tobacco smoke. So you have the time and the dilution dimension.
So for, at least Philip Morris, we use as a model for studying environmental

tobacco smoke something that we call room-aged sidestream smoke where we take fresh sidestream, put it in a room, dilute it, let it sit there for a finite amount of time, and then evaluate the physics, the chemistry, and the biology.
We have looked at the chemistry, the physics and the biology of all three of these materials.
Q Do things in the room or a room affect the creation of these things, of environmental tobacco smoke?
A They not only can affect the creation of the materials, but they can also affect the fate of the materials.
Q What do you mean "the fate of the materials"?
A For example, if I were to smoke a cigarette and then go home, my wife would probably smell my jacket and say, "You've been smoking." And that's because some of these materials absorb into your clothing. They absorb to my beard. And so it's taken out

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of the environment.
So things change as a function of time

depending upon what's in the room, how hot the room is, the humidity in the room, whether you have natural fibers or synthetic fibers. There is some very complex chemistry that goes on here.
Q And then with respect to, is it room aged?
A Yes. We abbreviate it RASS, room-aged sidestream smoke.
Q What use do you -- let me back up. How do you -- do you use this in the laboratory?
A Yes. And it took many years to come to the point where we felt comfortable that this was a reasonable surrogate for studying environmental tobacco smoke.
Q Let me show you for demonstrative purposes, Doctor -- can you see that?
A Yes.
Q Tell us what this picture is. What is this?
A This is the system that we use at INBIFO for evaluating environmental tobacco smoke RASS, room-aged sidestream smoke.
Q Let me interrupt you. I apologize. When you say "evaluate," for what purposes?
A To try to understand the chemistry, the physics, and the biology of room-aged

sidestream smoke.
Q Explain to us how you create this room-aged sidestream smoke.
A I think there is a cartoon of a burning cigarette. It's on the left right there.
Q Here?
A Yes. Right there. And these cigarettes are placed in a special smoking machine. And INBIFO engineers have designed and built and published on this. And you put the cigarette in, and the cigarette is lit, and then puffed according to either the Federal Trade Commission or an international smoking standard.
The puff is discarded. That would be the equivalent of mainstream smoke. That's discarded. Between the puffs, the smoldering cigarette, the sidestream smoke that's coming off is then captured in that hood.
Q This hood?
A Yes. And then pulled into the room with the little fan. That room, depending upon the experiment, can contain a variety of materials; fabrics, books, clothing, et

cetera. And it's of a known dimension, and the airflow is controlled. And so we can age the sidestream smoke in that room under various conditions, varying time or internal conditions.

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Once we've done that, there's an exit from the room.

Q Is that this?

A Yes. And that goes directly to that long cylindrical device.

Q Which would be this?

A Yes. What this is a depiction of is a system in which animals would be exposed to this room-aged sidestream smoke. And the animals, and they're rats in the case of these kinds of studies, are inserted with their noses into the stream of the smoke. So only their noses -- so this is what's called a nose-only inhalation. So you know for sure that the animal is alive and breathing, and that they're breathing in this room-aged sidestream smoke.

And the animals can sit there for six, seven hours a day, up to seven days a week at various levels of this room-aged

sidestream smoke, and you can do these studies with animals for a number of years.

Q When was this apparatus or equipment created?

A This was, the cartoon here, represents the culmination of about ten years, ten years' worth of work. So in the time that I've been at Philip Morris, this room has been in place, and studies have been going on, plus or minus a couple of years.

Q So am I correct the first thing that happens is to determine the chemistry and physical nature of ETS; is that right?

A Yes.

Q What's the next thing, the next type of test that was conducted at Philip Morris with respect to environmental tobacco smoke?

A Once we felt we had a handle or some reasonable understanding of the chemistry and the physical nature, was to try to figure out if we could come as close as we could to represent ETS exposure in test tube situations and in animal exposure situations.

Q Are the test tube situations referred to as

genotoxicity tests?

A Genotoxicity is just one kind of in vitro test that was carried out with this material.

Q And what were the results of those tests?

A The results of the genotoxicity tests with regard to room-aged sidestream smoke was that there was biological activity of that smoke with regard to genotoxicity.

Q And what does that mean?

A That's an interesting question. The test system that we employ is a standard testing system used and approved by government agencies around the world. It's the

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so-called Ames test. And in the Ames test -- and these are bacteria that have been specifically designed to fail with respect to -- it's very easy to produce genetic damage in these microorganisms, so they're exquisitely sensitive.

And so we have, following very specific guidelines, tested a variety of strains of this organism with and without what's called metabolic activation.

Many times many of the chemicals that

we might be exposed to are harmless. There is something that we do in our body that could activate them, this metabolism. And this metabolism can go several ways. It can activate them or it can inactivate them. And so we were evaluating this whole process using this system.

So you're looking at the potential for these materials to damage DNA.

Q And how did the results of these in vitro tests with respect to the room-aged sidestream smoke compare to the results of tests that could be or were conducted on mainstream smoke or sidestream smoke?

A Fresh sidestream smoke in relationship to these three kinds of smokes was clearly the most active in this genotoxic assay.

Q Do people encounter fresh sidestream smoke in real life situations?

A Unless you're a smoker, I don't think so.

Q And what, if anything, does the results of a test like this tell you about the relationship between that substance and its ability to cause cancer in people?

A Again, it's a measure of a biological

response. A biological response that looks at the potential for DNA damage. It is something that's used, as I said, by the government to screen for materials. Materials that would, say, be mutagenic.

Different classes of mutagens have been shown to produce cancers in animals. Others haven't. It depends on the class of compounds that you're looking at. There are compounds that cause cancer in animals that are not mutagenic, and there are compounds that are mutagenic that don't cause cancer. But it is a good indication that there is the potential for damaging DNA. And that's really all it should be used for.

Q So what's the next step then in analyzing room-aged sidestream smoke and its relationship to the cause or potential cause of cancer?

A We also look at something called cytotoxicity. Cyto meaning cell; toxicity meaning damage or death. And you're looking now at a different potential mechanism than

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the genotox test. You're looking to see whether inhaling or coming in contact with

this smoke material will damage the cell. Will it hurt it in some way? Will it eventually kill it, or will it kill it right away? That's really all you're assessing at that point.

Q And is that a standard test used to assess the toxicity of substances?

A Again, it's generally part of a standard testing protocol.

Q And what do you do with the results of that type of test?

A It factors into what is an overall evaluation of the material. It's just one other piece of information.

Q What's the next piece of information you try and develop?

A Well, in the case of room-aged sidestream smoke, we've carried out a series of what are called subchronic inhalation tests in rats.

Q Let me stop you right there. What does subchronic mean?

A It generally means that the animal is exposed for 90 days or less to whatever the material under evaluation. That's compared

to a chronic test in which you're exposing for, say, 12 months or a lifetime test, in which you're exposing for the life of the animal.

Q And tell us how these tests were conducted.

A The experiment was designed in a fashion in which you had animals that were just placed in those tubes and just exposed to fresh air. You had other animals that were placed in another set of tubes that were exposed to various concentrations of, say, room-aged sidestream smoke. And you had people that would watch these animals, observe them in terms of their overall behavior, because sometimes just looking at how an animal responds gives you some insight into terms of what might be going on.

In the case of a 90-day study, the animals would be exposed for 90 days. In the Philip Morris INBIFO protocol, they would be exposed seven days a week, six or seven hours a day.

We also have incorporated into this design what's called a post-inhalation period. And you're asking a question here,

so you've exposed the animal for 90 days. Things happen. Those things that happen, if you take the exposure away, what happens to the things that change?

And so that becomes -- has become an

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integral part of what we've ended up doing in terms of our evaluations here.

Q And when you do these types of studies, you told us about how the animals were placed in that machine. Why aren't animals exposed to smoke the way people would encounter environmental tobacco smoke?

A Actually we've -- we're doing an experiment that contains both the nose-only and what we call whole-body exposure. One of the difficulties with an animal like a rat, when you whole-body expose them, afterwards, when you take them out of the tube and put them back in their cage, they tend to sit there and clean themselves. You know, they like their fur, they preen themselves. And the materials that they're exposed to get deposited on their face.

They also have some other habits with regard to urine and feces that allows them

to also pick materials up that they've removed and then reincorporate them. So at the end of the day, you have a problem really trying to understand where they got their exposure from. Whereas, in a head-only system, you know for sure that their nose is in there.

In a whole body, their whole body is exposed, and they're cleaning themselves and they're doing other things with their feces and urine that complicate things. So you have a much more difficult situation to try to understand.

But having said that, we feel it was important to look at both, and we're currently doing -- we're currently doing that.

Q What were the results of the subchronic inhalation studies?

A The studies that we are reporting on actually will appear, I think, this month in Toxicological Sciences, which is a peer-reviewed journal of the Society of Toxicology. Basically found that there were small changes in the upper airways of the

animals indicative of some kind of irritation. And when you took the exposure away, those changes tended to disappear.

Now, the levels at which these animals were exposed are between 100 to 1,000 times higher than has been reported by the EPA, for example, as the highest average dose that a human being has been reported to be exposed to. So the highest level was between 100 to 1,000 times higher than people have been exposed to.

Q Did any of the subchronic studies demonstrate lung tumors or lung cancers?

A No.

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Q Did any of the subchronic studies indicate any cancerous or precancerous changes in the pathology of the animals?
A The only changes that were seen were changes indicative of irritation. We saw some hyperplasia in some parts of the respiratory, upper respiratory tract, primarily the nose. The nose was affected. But those tended to go away after the exposure period.
Q And the results of these subchronic tests

have been submitted to a journal for publication?
A Actually, they've been submitted and, as I said, they should be coming out this month.
Q What's the next step or the next piece of work that the company has done in this area?
A We started several years ago, even in the face of this observation, and there have been other publications in this area that have shown there are small irritative effects that tend to go away. There's no progression, no tumors. We still felt it was important to do a lifetime study.
And it is no simple matter to put together the necessary expertise and resources to do that. And it took us several years to design such a study. And because of a problem with a rat that we were using, we had to switch to a new rat. And the reason was that we wanted to go out as long as was possible.
A rat generally lives, a laboratory rat, about two years. And given the constraints of this system, the size of the tube, we needed to have a rat that would not

grow too big and too fat to fit in this tube and yet live long enough that at the end of the study we would have enough animals left to have a meaningful evaluation.
MR. MOTLEY: Your Honor --
Are you done, Doctor? I'm sorry.
THE WITNESS: I'm sorry?
MR. MOTLEY: Are you done with that answer?
THE WITNESS: No.
MR. MOTLEY: Because I need to approach, Your Honor.
THE COURT: All right.
(Bench discussion)
THE COURT: We need about ten minutes, ladies and gentlemen. We're going to take another break at this point. Sorry. You can leave your notes on the chair. Don't talk about the case. We'll come and get you as soon as we can.
MR. CASSELL: All rise.
(Jury not present)
THE COURT: You may step down. All

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right.
Jury is not present. Be seated.
CARCHMAN-DIRECT
7603
There's an objection, Mr. Motley, based on the fact you were unaware of this study. Is that --
MR. MOTLEY: Well, we would ask the witness to be asked to absent himself.
THE COURT: I'm sorry? You want him --
MR. MOTLEY: Out.
THE COURT: Oh. I didn't know if you said you wanted him here or not.
MR. MOTLEY: No. No. Judge. I meant that he would absent himself.
THE COURT: All right.
MR. MOTLEY: Your Honor, we subpoenaed the witness to bring certain things to the deposition that we took in this case. I'd like to file that subpoena with the Court to let you see.
THE COURT: All right.
MR. MOTLEY: I don't know where this is going. I mean, this may be much ado about nothing on my part, but if he's got some kind of study that he's claiming they got a final report to or something like that, it wasn't provided to us.
CARCHMAN-DIRECT
7604
And I didn't complain about the subchronic inhalation test because that didn't make much difference to me because that's not designed for cancer.
But this lifetime study he's talking about, Your Honor, you see, we asked for anything he's relying on. Anything. And that was not forthcoming, was not produced. We asked what he was relying on in his testimony on page 8. There is no mention here of this lifetime study, Your Honor.
Here, if I might --
THE COURT: Thank you.
MR. MOTLEY: If it wasn't -- again, I don't know if -- I don't want to waste Your Honor's time if Mr. Ohlemeyer is not -- for all I know, this study is still going on. I don't know. If it's not still going on and if there's a report, the defendants have not produced it.
THE COURT: It sounds like the study is finished, Mr. Ohlemeyer. Can you help us out here?
MR. OHLEMEYER: To the best of my knowledge, Your Honor, the study -- first of
CARCHMAN-DIRECT
7605
all, here is his disclosure. Here's what we told them.
THE COURT: Thank you.
MR. OHLEMEYER: "The study has either just finished or is in the process of

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being finished and submitted for publication."

MR. MOTLEY: In his deposition -- Your Honor, they got a duty to seasonably produce these things to us, and it's not like the situation with the doctor that did the study in the middle of the trial whose deposition we didn't take. This is a man whose deposition we took. Ms. Ritter took the deposition. We served a subpoena on them. They produced certain things pursuant to the subpoena. The subpoena is ongoing. If there's some kind of written study he's going to try to put into evidence here for this witness --

MR. OHLEMEYER: I'm not.

MR. MOTLEY: But he can't rely on something, Judge, he's obviously got writing or results or data or something.

THE COURT: I thought that's where

you were going.

MR. OHLEMEYER: Your Honor, first of all, I'm going to ask him about the study that they're doing and the results of it. I'm not going to put any study into evidence but he gave that piece --

MR. MOTLEY: And the results of it.

THE COURT: Are you going to ask him about the results?

MR. OHLEMEYER: Sure. He gave that to --

MR. MOTLEY: I object to that.

MR. OHLEMEYER: He gave them pieces of that data in the deposition. Some of the exhibits to the deposition are data from their own unpublished work to date.

MS. RITTER: I don't think it's the same study.

MR. MOTLEY: No.

Once again, Judge, here we go. They don't even have a finished study, according to Mr. Ohlemeyer. They don't produce it to us pursuant to the subpoena in a form that's recognizable. They don't -- he's asked what he relies on. You don't hear a word about

that at page 8.

And how can we possibly prepare for a study that's in progress here, Judge, in the middle of the trial now we're going to hear about a study that he may or may not, according to Mr. Ohlemeyer, have results for. I don't mind him talking about the study. It demonstrates, you know, they can argue that demonstrates they're trying to find something out. But I do object to coming in here and dropping in our lap in the middle of the trial, for the second time, additional scientific data.

MR. OHLEMEYER: First of all, Your

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Honor, they didn't subpoena the witness. They served us what purports to be a Notice of Deposition that was dated December 2nd. I think it was received at some point after midnight on that day for a deposition that was scheduled at their convenience on December 4th.

But be that as it may, they have our 36(b)(4) response. They did conduct a deposition. And they had the chance to ask him about anything they wanted to ask him.

MS. RITTER: I asked about it.

MR. MOTLEY: We asked him what he relied on, Judge.

THE COURT: Looking at page 9 here, the last row, "Measurements of the extensive measurements of smoke constituents that we have ongoing now in laboratory studies."

MR. MOTLEY: Smoke constituents. We ain't talking about smoke constituents. We're talking about killing poor little rats from sidestream smoke off of Marlboro.

MR. OHLEMEYER: I don't think the levity advances --

MR. MOTLEY: I'm not being levitous or whatever the word is for it.

MS. RITTER: I asked for the material.

MR. MOTLEY: We asked for the material and it wasn't forthcoming. Judge, and I don't think, with all due respect, that ought to be the end of it. They can't walk in here in court with these witnesses, time and again, Judge, with stuff they haven't given us.

MR. OHLEMEYER: They've asked for

documents that we provided to the witness. They asked for documents he specifically reviewed in preparation. They asked for documents prepared in connection with the case. They asked for medical and scientific articles that he anticipates referring to specifically and reports prepared specifically for the case.

THE COURT: The argument is they took a deposition in December, they asked him upon what he was going to rely, and he didn't say anything about the study.

MR. OHLEMEYER: But my response to that, Your Honor, is they had a list of exactly what he's been talking about, including studies conducted at Philip Morris.

MR. MOTLEY: Well, how -- there's a thousand studies at Philip Morris.

THE COURT: Let him finish. Let him finish.

MR. OHLEMEYER: Well, specifically Dr. Carchman will discuss laboratory

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experiments, especially inhalation studies in which exposures of animals to aged and

diluted ETS surrogates of various concentration. Such experiments include ones performed in Philip Morris' laboratories as well as those conducted by other investigators.

If they didn't ask him about that at the deposition, that's not entirely my problem, Your Honor.

MR. MOTLEY: Judge, we asked questions reasonably expected to have discovery given to us. And he was not forthcoming. They were not forthcoming. And the only time they come forth is when they're in the middle of a trial.

MR. OHLEMEYER: I disagree with that characterization completely. They were given his 36(b)(4) response. They've deposed him in other cases.

MR. MOTLEY: Oh, now, wait a minute. Wait a minute. That is absolutely untrue, Mr. Ohlemeyer. We've never taken Dr. Carchman's deposition.

MR. OHLEMEYER: The fact of the matter is, Your Honor, they had his 30- -- they had that sentence. I'm not going to

tell Mr. Motley how to practice law, but when I ask a witness that question --

THE COURT: Let me see that again.

MR. OHLEMEYER: -- I take --

MR. MOTLEY: Judge, what's the purpose of serving a subpoena on a man and asking for the documents? They didn't give us this subchronic inhalation test, either, which is finished, according to him. And that was -- we asked him for anything he was going to rely on. That's finished. He said it was published. They didn't give us that.

So now they've got one that's finished enough for him to give us the results but it hasn't been published. They're going to come in here and drop this in the middle of the trial. It's just not fair, Judge. He's got plenty of other things he can rely on, he doesn't have to rely on that.

MR. OHLEMEYER: Mr. Motley keeps talking about these questions --

MR. MOTLEY: Judge, on page 56, he sent us one unpublished study right here, but he didn't send us this.

MS. RITTER: I specifically was

asking him about things he is going to rely on. Because to say his opinion and not have the study isn't helpful. That's why we served the notice. I specifically asked him what he's relying on.

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Then in his report that they gave us at the deposition via fax, he specifically referenced an unpublished study, a different unpublished study. I raised that at the deposition and said we have requested things, Mr. Ohlemeyer. Maybe it's an oversight. I need to get it. After the deposition I was forced to sign some confidentiality agreement to get that one study.

My motivation and aggressiveness to try to get this underlying data is clearly manifested in this deposition and yet here we have testimony about some recent studies that we just -- we would need the data.

MR. OHLEMEYER: Those questions, Your Honor, dealt with P53.

MS. RITTER: That's right. That's what I'm saying. But it was a follow-up on.

MR. OHLEMEYER: Different issue.

MS. RITTER: It was a follow-up on, if he was going to rely on data, I wanted the data. That was why we served the notice. That's why I went through the series of questions. That's why I asked him if he was going to rely on. And this is not referenced in the written report that he prepared in this case. There's also a written report that doesn't talk about this beyond the disclosure.

MR. OHLEMEYER: What it describes is exactly how lawyers conduct discovery. He prepared a report on the P53 that relates to Dr. Cagle. Ms. Ritter asked him questions about something he used in that report, which is this unpublished study. She said "Give it to me" and he did.

THE COURT: Let me see your discovery, your expert disclosure again.

MS. RITTER: Because that's the only way I knew about it, because it came out because he happened to mention it in his report. I couldn't ask him about underlying data. I already asked him to bring any data he was going to rely on.

I don't know what we would have to do to get the data that he would rely on. Just take his word for it. You didn't produce it in the case. You said nothing was relevant after 1992. I got boxes of stuff on ETS before 1992.

MR. MOTLEY: You understand, Judge, we asked for this also -- excuse me one second. We asked for it in the request to produce; they said they wouldn't give us anything after 1992. Okay. We've got those discovery responses.

So if they're not going to produce anything after 1992 on grounds that it's not

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relevant, why would that put us on notice that he's going to use something that ain't even finished yet? I mean, they've got us in a Catch 22 here, Judge. It's simply not fair.

MS. RITTER: I figured that disclosure referred to something.

THE COURT: Wait a minute. Wait a minute. Wait a minute.

Mr. Ohlemeyer.

MR. OHLEMEYER: First of all, the

plaintiffs spent four weeks persuading the court and trying to persuade the jury that everything that happened after 1992 has some relevance to this lawsuit.

Secondly, we specifically told them what Dr. Carchman was going to talk about. They specifically had an opportunity to depose him based on that disclosure. They could have asked him anything they wanted to ask him.

This subpoena they keep talking about isn't a subpoena and it doesn't ask for what it is they're complaining about.

When Ms. Ritter asked for things that Dr. Carchman discussed at the deposition, she was provided with it. She didn't inquire about this type of data.

THE COURT: You're representing this is your disclosure right here.

MR. OHLEMEYER: Yes, it is.

THE COURT: Ill tell you, something this important should have been in this disclosure, and it is a very long stretch for me to look and find this test in this disclosure. And I see what you're saying.

Ones performed in Philip Morris Laboratories.

MR. MOTLEY: Do you know how many studies that is, Judge?

THE COURT: I know. I know.

MR. MOTLEY: It's 10,000 studies. And if he says that, during the course of this trial, Your Honor, that you ruled that things were current were relevant to certain issues, why didn't they supplement, then, their discovery once you made that ruling and give us post '92 stuff.

THE COURT: Is that the only spot you're looking at?

MR. OHLEMEYER: Your Honor, this is the interrogatory response in this case. And it discusses Dr. Carchman's expected testimony based upon analysis that he had done when he testified on November 11. There's the paragraph about the animal experiments, including one done at Philip Morris. There's a paragraph about the EPA, ETS, CTR research. And based upon his

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background, his education, his knowledge and anything else conducted by Philip Morris

scientists.

They then said produce him for a deposition. They didn't say -- they could have asked questions all day long. They chose to do it by telephone, not in person. They chose to let us know about that the morning of the deposition. They didn't ask for a chance to take a day, two days, three days.

These guys are experienced lawyers, they know how to conduct depositions. And I think they were on notice in this case that this man would testify about these types of things.

Obviously, everything he's going to talk about isn't listed here. That's not what the law requires. It requires subject matter, opinion, basis of opinions.

And this man is also listed as a witness who is fairly described as a fact witness as well as somebody who would offer opinions. It's a fact.

MR. MOTLEY: Your Honor, I don't have any objection to talking about the study in general. I got serious objections

to these results coming in. There is no basis, no reason under these rules of discovery, both for this case specific, Your Honor, and as a general proposition from your Rules of Civil Procedure why, once Your Honor ruled post '92 was relevant, these guys didn't say, okay, here is ten more boxes of stuff that is reasonably responsive to your request to produce all of these kinds of studies. He didn't produce a single one after 1992, Judge. Not one.

MR. OHLEMEYER: Because discovery is closed.

THE COURT: I know.

MR. MOTLEY: Discovery is closed. It's always -- discovery is ongoing, Your Honor, even at the time to take discovery is closed. Something that was filed before discovery was closed, there is an obligation, Your Honor well knows, to seasonably supplement when it becomes relevant.

THE COURT: Well, thank you, gentlemen and lady.

What we know is that in my judgment it

was not mentioned in the expert disclosure. It was not mentioned in the deposition. The results of the test, if there are results, would be unfair at this point to put before this jury. He can tell us about the fact

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they did a test and, in fact, he has told us about that, but the results won't come in.

MR. OHLEMEYER: What about the fact that it's been submitted for publication?

THE COURT: He's already told us that. I can't do anything about that now. He's already told us.

MR. OHLEMEYER: All right.

THE COURT: I'm not going to order that stricken.

MR. OHLEMEYER: I have a matter. Can I bring a matter to the Court's attention? All right.

THE COURT: Yes, sir.

MR. OHLEMEYER: On cross-examination, Your Honor, I expect Mr. Motley to confront this witness with a videotape known as the "Death in the west" program.

THE COURT: "Death in the West"?

MR. OHLEMEYER: "Death in the West," Your Honor, quite simply, is a journalistic fraud. It was a television program --

MR. MOTLEY: I have no such intention, so we can save that time today.

THE COURT: Thank you.

MR. MOTLEY: Not with this witness.

MR. OHLEMEYER: At some point, Your Honor, we have to talk about this. And I don't want to burden the Court with it now but I think Mr. Motley is on notice that no use of this videotape or description or reference to it should be made before we have a chance to talk about it.

THE COURT: We will discuss it before it's used.

MR. MOTLEY: Yes, of course, Your Honor. I understand.

THE COURT: Bring in the jury.

MR. CASSELL: All rise.

(Jury present).

THE COURT: Be seated. All right. Jury is now back.

Again state your name, Doctor.

THE WITNESS: Richard Carchman.

THE COURT: Thank you, sir.

Mr. Ohlemeyer.

MR. OHLEMEYER: Thank you, Judge.

BY MR. OHLEMEYER:

Q Doctor, what are nitrosamines?

A Nitrosamines are a large family of chemical molecules that are nitrosated amines.

Q And in what substances can nitrosamines be found?

A It can be found everywhere in the environment and, in fact, we make them ourselves.

Q Is there a nitrosamine known as NNK?

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A Yes, there is.
Q What is NNK?
A NNK is a nitrosamine that is specific to tobacco.
Q And does it occur in either sidestream or environmental tobacco smoke?
A Yes.
Q Why and how and in what quantities?
A There are two ways for NNK to get into smoke. One, it is found in tobacco itself. Two, when you burn tobacco, you can do one

of two things: You can transfer the NNK that's already in the tobacco into the smoke, or you can create it in a process that could involve pyrolysis or combustion.
Q And can you remove NNK from smoke?
A Only insofar as you can remove the particles of smoke. The NNK in smoke is generally associated with the particles. So if you have a filter that removes particles, you're going to remove NNK.
Q And has the relationship between exposure to NNK and the subsequent development of cancer been studied?
A It's been studied extensively in animals.
Q Under what circumstances?
A A variety of different kinds of animals; mice, rats, hamsters, different routes of administration, orally in the drinking water, injection, any number of ways.
Q Has Philip Morris conducted research in the area of nitrosamines?
A Yes.
Q When did Philip Morris begin doing that kind of research?
A I think in the early '80s or late '70s when

the methodology for actually being able to measure them became -- became well established. The amount of NNK that's found in cigarette tobacco or in smoke is a very, very small number and, therefore, difficult to measure.
Q And how does it compare to the amount of NNK that is present in other substances?
A Well, the only place NNK is found is in tobacco and tobacco-derived smoke.
Q How small is very small?
A If I take a gram -- 2.2 kilograms, I think, is one pound. So I weigh a little over 100 kilos, unfortunately, so I weigh 220 plus. A gram is one-thousandth of a kilogram. That's a gram. This is one-billionth of that gram. So it's one-trillionth of a gram. It's very, very small, very, very small amount.
Q Dr. Carchman, let me ask you about something known as, excuse me, P53. What is P53?
A Well, P53 is both a gene that's found in our chromosomes, each and every one of us has

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it. It's found in chromosome 17. We each should have been 46 chromosomes, and they're

numbered 1 through 23, and you basically have two of each. It's located on chromosome 17. And, in fact, the chromosome has arms, and it's located on one of the short arms of this chromosome.

So it is a gene that's located on a chromosome that we all -- we all have.

Q What's its function? What's its normal function?

A P53 gets its name because it makes a protein. That protein has a weight of 53 thousand Daltons; so P53, P for protein, 53 for the molecular weight. And its function involves regulation of the cell cycle. When we have a cell in our body that is dividing, it goes through a cycle. P53 controls that cycle. If the DNA in that cell is damaged, P53 is one of the proteins, only one, but it's an important one, that's involved in stopping the cell from going through the cycle and trying to repair the damage.

If it can't repair the damage, it gets involved in another process that kills the cell. So if you have a cell that the DNA is damaged, it somehow turns on P53. Nobody

really knows how. It goes in. It either stops the cell from dividing, repairs the damage, or, in essence, kills the cell. It is what's called a tumor-suppressor gene. It's been around in terms of this kind of name since the late '70s.

Q How does a P53 gene become abnormal?

A There are at least two mechanisms for it to become -- three, sorry, three mechanisms for it to become abnormal. One mechanism is that it could be mutated. That is, either something inside your body or something from outside your body can make a change in that gene, in that chromosome.

Q So something internally?

A Internally or externally. And when that kind of change happens, and it has to be a certain kind of change, P53 is not active. It doesn't do what it's supposed to do. So that's one.

The second is that P53 is part of a large group of materials that control cell growth, cell division, and try to prevent cancer. So there are other proteins that interact with P53 that bind it in your body.

So when those proteins bind to P53, they inactivate it. And those proteins are controlled by lots of other things. They're found on different chromosomes, and there are different things that turn them on or --

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turn them on or off.
And the third -- the third mechanism involves the fact that P53 is just one of several important factors that control this whole process that don't involve the binding of P53, but work what's called downstream of where P53 is operating. And some of those could involve onc genes or oncogenes as they may be called.
Q How would you describe that?
A I would call it a family effect. P53 is one member of a very large member of things that we have in our body that help us. And P53's probably original function had nothing to do with cancer, but it turns out from a survival perspective, evolutionary perspective, it just picked that up as time went on. It's found in lots of things besides people.
Q Tell me how a P53 gene can be mutated

internally.
A When you eat, eat food, that food is metabolized. If you have a Snickers bar or M&Ms, that sugar is metabolized to other substances. In the process of that metabolism, your body creates chemicals that are very reactive that have been shown to damage DNA. And it's not -- it is pretty well known, if not totally established, that these events can occur.
So in the normal course of day-to-day living, it's been estimated by scientists in the literature that you have DNA damage every day, maybe 100,000 times a day, every single day. Most of that ends up being repaired. P53 is one of those things that helps in the repair. But if P53 is a target, then P53 won't work.
So inside us, when we metabolize food, you create these very reactive materials that can inactivate P53.
Q Can you be born with a mutation in your P53 gene?
A Unfortunately, there is a syndrome called Li-Fraumeni syndrome, in which these people

have a defect in the P53. If they live to be 30 years of age, they have a wide variety of tumors, a significant percentage. If they live to be 65, 95 percent of these folks have cancer. So it's a very important, a very important gene in terms of trying to protect the body against developing cancer.
Q Tell us how external things mutate a P53 gene.
A So if you're walking outside here in Muncie, Muncie, Indiana, and breathing the air, there are materials or chemicals in the air. If a diesel car or diesel bus goes by, there

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are diesel particles and diesel materials. Those materials, if they get into your body, either by inhalation or ingestion; or if you make a good charbroiled steak on the grill that has lots of these chemicals in it, you introduce those chemicals into your body. Or if you drink the water, that I would love to have another glass of, there are those chemicals in that water that can do basically the same, the same thing.

Q Is the process by which a mutation occurs

and cancer results this simple or is it more complicated?

A It's really much more complicated, much more complicated than that.

Q Can mutations in your P53 gene occur without the subsequent development of cancer?

A Yes.

Q Are there substances in -- strike that.

Tell us what benzo(a)pyrene is, Doctor.

A Benzo(a)pyrene is a chemical member of a very large family of materials called polyaromatic hydrocarbons. Any time you burn anything, whether it's tobacco or fuel or leaves or your charcoal-grilled steak, your going to generate benzo(a)pyrene, BaP.

Q So the substance benz(a)pyrene or benzo(a)pyrene is not unique to cigarette smoke?

A Any combustion of any organic material is going to produce benzo(a)pyrene.

Q How does the amount of benzo(a)pyrene in cigarette smoke or environmental tobacco smoke compare to the amount of benzpyrene in either ambient the air or food or water?

A There have been studies published that have

looked at what, in the United States, what the average person might be exposed to with regard to benzo(a)pyrene. I think the EPA and some scientists at Oak Ridge are probably the most prominent people in the area.

And what they have found is that 98 percent of the benzo(a)pyrene that you and I are exposed to come to us from the diet. Two percent come by breathing, just the air. In a city like Muncie, or where I come from in Richmond, 2 percent comes from that.

If you look at the levels of benzo(a)pyrene that have been measured in ETS or even in the material that we use, room-aged sidestream smoke, either you can't find it or it's there as a small piece of what you would inhale normally in breathing. So if 2 percent of what you're exposed to with regard to benzo(a)pyrene comes from inhalation, ETS exposure would be some small piece within that 2 percent.

For mainstream smoke, a person smoking

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20 cigarettes a day, if you assume they inhaled everything they smoked, and none of

it got out, that would change the total body burden of benzo(a)pyrene by 16 percent. That's a number published by the -- in this paper by the EPA.

Q Is benzo(a)pyrene believed to be associated with mutations in P53 genes?

A Yes.

Q And are there other substances besides benzpyrene that are believed to create mutations in a P53 gene?

A Yes.

Q Are mutations in the P53 gene only found in certain types of cancer?

A No.

Q What types of cancer have been associated with -- in what types of cancer have researchers identified mutations in the P53 gene?

A In the largest database that exists in the world of P53 mutations in human beings, which is on the Internet. You just have to dial up the right web site. It's all free. What you find is that mutations have been reported, this January over 8,000 mutations have been reported in the scientific

literature. Of those 8,000, they have found mutations in everything from the adrenal gland, which I talked about earlier, this little gland that sits above the kidney, to the vulva, from A to V and everything in between.

And that comes out of a relational database that was created in 1991, and it's housed as part of the World Health Organization in Lyon, France, at the International Agency for Research on Cancer. It's publicly available.

Q Tell us what the International Agency for Research on Cancer is. Is that IARC?

A IARC, yes. It's part of the World Health Organization, and the United States is -- the United States, Germany and Japan are probably the major financial contributors to this agency.

Q And this database is -- what's the purpose of this database?

A When it became apparent that the P53 mutations were being picked up in something like 50 percent of all of the human cancers -- in a general way, that had been

looked at. And the fact that the mechanism of this protein seemed to be controlling cell growth and dealing with mutational-type damage, somebody said maybe this is important either in terms of mechanism,

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understanding how cancer is being caused, and potentially important in terms of therapy.

And so as part of that, they created this very, very large database that they update now every two years, in July and January. And they have very strict criteria for the inclusion of this information in the database. And it has very specific, very specific goals associated with it.

Q Okay. So am I correct that there are certain types of cancers -- let me ask it this way, Doctor: Are there cancers in which no mutations in P53 genes have been observed?

A Yes. As I said, it's found in about 50 percent of the cancers, which then by difference means about half the number of cancers have not been found to have mutations in P53.

Q Can you find mutations in P53 genes in cells that are not cancerous?

A Yes.

Q And I think I asked you this in a different way, but is it fair -- am I right that a mutation in the P53 gene is not all it takes to create cancer?

A That's correct.

Q And can cancer occur, including lung cancer, without mutations in the P53 gene?

A Yes.

Q How is it that you, specifically Dr. Carchman, at Philip Morris got involved in looking at the issue of P53 and its relationship to cancer?

A As part of my responsibilities, I read the literature, I attend meetings, I have fellow scientists attend meetings; and it was apparent to me and some of my colleagues that this was one --

MR. MOTLEY: Excuse me, Your Honor. I don't mind the witness describing what's apparent to him, but he shouldn't drag along his colleagues if he's going to offer some opinions. It's hearsay.

THE COURT: Just tell us, not what's apparent to your colleagues.

THE WITNESS: Thank you, Your Honor.

A It was very apparent to me that P53 was one of the emerging areas of basic research that could be very important in trying to understand both cancer and carcinogenesis and what role might be associated with smoking or smoking products.

Q And how did that become apparent to you?

A By reading the literature, by attending -- by attending meetings and reading trip reports.

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Q What investigation did you make into the relationship between P53 mutations and substances like benzo(a)pyrene?

A When -- over the years, there have been evaluations of benzo(a)pyrene going on within the company. When P53 became a very hot topic, oh, less than two years ago, I guess, in a Science report by Denissenko and colleagues, I actually found myself on an airplane with several of my scientific colleagues heading to La Jolla to meet with

Nobel Loriette and two other scientists to ask their opinion and ask their help in helping us try to understand what was going on with this particular study which reported using a technique that they had created, nobody else had this methodology at that particular time, and trying to understand what the meaning of their observations and conclusions were.

We came back from that trip, and we set up a team of individuals to do a complete survey of the P53 literature that continues to this date. I called my colleagues at INBIFO. They had already established a P53 assay at INBIFO as part of this RASS ETS exposure study that we were looking at. And it continues to this day.

We have access to this IARC database both in Richmond and in Europe, and we try to keep as much as we can up to speed on everything that's coming out, both in the published literature and in the meeting literature. For instance, the Society of Toxicology meeting just ended in Seattle. The American Association of Cancer Research

meeting is about to take place in New Orleans. And so we will -- we cover all of these meetings. We go speak to the scientists who are publishing in this particular area, for example.

Q What, if anything, is a G to T transversion as it relates to the issue of P53?

A The DNA in our body is really composed of four bases. G stands for guanine, T stands for thymine. You have two other bases, A for adenine, and C for cytosine.

When a molecule, a mutagen is activated and binds to one of these bases, to A, to G, to C, to T, you have the normal molecule that's there and then you have something stuck on it that doesn't belong there. And it's stuck very tightly.

You have proteins in your body, P53 is one of them, that normally monitors things that don't belong. And so it will come along and hit a bump, like on a railroad track. There's a track out of kilter. It knows it. It fixes it. If it fixes it

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right, not a problem. If it fixes it wrong, you could have a problem.

The G to T is a problem that was identified, except it wasn't fixed right. The G was not replaced with another G. It was replaced with a T. Okay. And this kind of change, which goes in this direction, is called a transversion.

There are other kinds of changes, but these changes, in general, is you put something there that wasn't there before. That one simple change from a G to a T has a potential for causing dramatic changes later on.

I don't know if you want me to --

Q Let me ask you this: Is this topic something that people are studying essentially as we speak in the world of science?

A Yes.

Q Is it -- could you fairly describe it as molecular biology?

A Yes.

Q And when people use the word mechanisms or mechanistic experiments, is this that type of experiment, the study of the mechanisms of cancer?

A It's part of it.

Q What, if anything, causes or is associated with G to T transversions or can it be determined?

A What happens when you have a G to T transversion, P53 gene that has Gs and Cs and As and Ts, make this protein P53. The protein is made of amino acids. Three, 400 amino acids. Each amino acid is lined up in a very special way. And when you have them all lined up in a special way, it looks -- if you're making a glove for a right hand, it could look like a glove that a right hand would fit into.

If you put in one wrong amino acid in a very strategic place, you could end up with a glove in which the thumb is over here and the hand won't fit in it. So one amino acid change could have a very dramatic effect on the structure of the P53 protein. And if the structure is affected, then the function is affected. It's not going to work, or it's not going to work as well. But it has to be not just the G to T. It has to be in a very special part of the gene, and it has

to be a change like this that then is translated to the next cell.

If this cell were to die, we wouldn't care. It would die. The fact that the cell continues to grow means that this change is

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now repeating itself, and that the daughters, the children of this original cell, will continue to have this particular change. And the protein will be changed and the activity of that protein will be changed.

Q Does a change in that part of the cell mean that the cell is going to eventually become cancerous?

A No.

Q In this study of P53 and its relationship to cancer, have observations been made as to how often some of these changes are observed in certain types of cancer?

A Yes.

Q What -- and is that information in the database you described to us?

A Yes.

Q Are there certain types of cancers in which these types of changes occur more frequently

than other types of cancers?

A Yes.

Q What types of cancers are they?

A If we look at lung cancer, for example, the major mutation occurs at codon 273 within the P53 gene. That is probably the number one mutational site.

Q Let me show you, Doctor, a chart, and ask you if you can explain this to us. This is a table essentially that you prepared?

A Yes.

Q Tell us what it is.

A This comes from this large relational database of over 8,000 human tumor reports related to P53 mutations. And as the header says, this is the incidence of P53 mutations in human lung tumors from smokers.

So you can ask the database of the 8,000 mutations that you have there list for me those that report smoking, and that's all you do. You just put that in and out comes a figure which has been put in tabular form.

Q Let me ask you a question. What is a codon?

A This G to T transversion that we're talking about and the amino acids, a codon

represents three of these bases, Gs, Cs, Ts, As, it could be all Gs or all As or all Cs or all Ts. This has been known for 45 plus years.

So one amino acid is coded for by three of these bases. So it's a codon, it's a triplet, three bases, code for one amino acid. So that's why when you change one of the bases in the codon, put another one in, it's coding for not this amino acid, but that amino acid.

So that's what a codon is.

Q What do you mean by hot spot?

A Well, a hot spot seems to be an area that

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has a high frequency of change reported with it.
Q And am I correct this is information about cigarette smokers?
A That's correct.
Q What is the significance of these numbers under codon?
A Each one of those numbers represent one of these codons in the P53 gene. The region of this gene that most people look at for changes covers something around from codon

100 to codon 300 something. And so 273 is a defined codon in the P53 gene. You can make a cartoon that stretches out the gene and it starts from point A and ends at point B.

The region that people focus on is right in the middle of this gene, and this is the region that binds to the DNA when there's a problem. And this region is the most conserved from an evolutionary sense. This is found not just in people. So it's felt to be very, very important. And so people have focused their attention on looking for changes in those regions.

And so 273 is, in terms of all of the literature that currently exists in this database, if you're going to see a P53 mutation, it's going to have the highest frequency in codon 273.
Q And am I correct that -- does the G to T transversion occur at each of these codons or only in specific codons?
A It can occur at some of them, but I don't think it necessarily occurs at all of them.
Q And is it fair to say, Doctor, that a mutation at codon 157 is the seventh most

frequent mutation that's observed in these tumors that are part of this database?
A That's correct.
Q Now, am I correct, Doctor, that there have been mutations in each of these codons, 273, 248, 245, 179, et cetera, observed in other types of tumors besides lung tumors?
A That's correct.
Q And, again, what types of tumors are those mutations observed in?
A Breast cancer, liver cancer, ovarian cancer. There's a whole list that you could basically ask this database to print out and get that information from.
Q And can you do that codon by codon?
A Yes.
Q Let me show you another chart, Doctor, that focuses on codon 157. Where does this information come from?
A It basically comes from the same IARC database.
Q And what it does is it lists tissues where cancers had been observed?

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24 A For codon 157.
25 Q And identifies how frequently those

1 mutations occur in different types of
2 cancer.
3 A That's correct.
4 Q And codon 157 mutations have been observed
5 in lung cancers?
6 A Yes.
7 Q They've been observed in breast cancers?
8 A Yes.
9 Q Pancreatic cancers?
10 A Yes.
11 Q Stomach cancers?
12 A Yes.
13 Q Uterine cancers?
14 A Yes.
15 Q And a variety of other cancers.
16 Let me ask you this then, Doctor: Are
17 you familiar with an analysis of genetic
18 material or tumor material conducted with
19 respect to tumor taken from Mrs. Wiley?
20 A Yes.
21 Q And have you reviewed the data created by
22 the people who did that analysis?
23 A I reviewed some material that was in a
24 transcript that was given to me, yes.
25 Q And did it include the data of the actual

1 analysis?
2 A Yes.
3 Q Tell us in simple terms how that kind of
4 analysis gets conducted.
5 A You can take the tissue material from an
6 individual, and then isolate out the DNA
7 material that you're potentially interested
8 in. And then using a technique called PCR,
9 or polymerase chain reaction, you can take a
10 small piece of this under very careful
11 conditions, and you can make lots of it, so
12 you actually measure some things with it.
13 So you don't need very much.
14 You have to be very, very careful,
15 very, very precise because this stuff is
16 found in the cells that we shed, the hair
17 that's in -- on our heads, if we have hair
18 on our heads. And so you have to be very,
19 very careful how you do this reaction. But
20 it's done. You just have to be very careful
21 how you do it.
22 Q What kind of laboratory does it?
23 A Well, the laboratories that I'm familiar
24 with are generally research laboratories.
25 Q And what kind of data is actually created?

1 A Well, depending on precisely how you do it,
2 you can sequence, look at every single base
3 in the entire P53 gene; you could look at
4 parts -- parts of that gene.
5 Historically people have recommended

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looking at a certain region of the P53 and it follows certain landmarks within the gene, say, from something called exon 4 to exon 8. There are 11 exons in P53, but for a number of reasons people are focusing on this exon 4 to exon 8.

It's no more than a road map in where to look. This is the region that's important for P53 to bind to DNA. So you look generally at these within this region. And it's recommended that, when you do this test, you confirm it by at least one more additional analysis.

Q What do you mean by confirm it by an additional analysis?

A Because it is not the simplest thing in the world to do. It's very, very tricky. You can get false positives and false negatives, depending upon what particular enzymes you use, the conditions of this incubation, the

tissue.

You have to be careful when you're dealing with a tissue like a tumor that's composed of many different kinds of cells. Some are cancer cells, some aren't cancer cells. So you have to make sure that you're targeting the cancer cell, if that's what you're interested in. So you can create artifacts, if you're not careful.

So let's say you do this and you think you do it as best you can. You should do an independent run to make sure you've done it right. If you don't see what you saw the first time, then you've got some problems, technical problems or other problems you need to work through to figure out what's going on.

And then sometimes if you're really scrupulous, you do not just the PCR, you do the whole sequencing of the gene or the whole sequencing between exon 4 and 8.

Q With respect to the analysis that was done on Mrs. Wiley's tumor material, were any mutations observed at codons 273 or 248?

A If I remember correctly, they only looked at

two exons, exon 5 and exon 6. And so I don't believe you would see, if there were those changes, you wouldn't see them in what they looked at.

Q Have G to T transversions been observed or identified in cancers, in lung cancers that have been associated in this database with exposure to substances other than cigarette smoke?

A Yes.

Q What types of substances?

A Aflatoxin, which is a normal material that we eat when we eat peanut butter or peanuts or grain cereals. It's a normal fungal

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by-product that's sort of everywhere. In countries of the world in which you have a lot of this, there's a lot of liver cancer. It's a codon 249, seems to be the target, and it's a G to T transversion, just as an example.

Q Have chemicals known as nitrosamines been tested to see if they mutate certain genes at certain points?

A Yes.

Q And what type of mutations are observed when

those types of chemicals are used?

A They're not.

Q They're not what?

A They're not observed.

Q So in experiments using nitrosamines, are G to T transversions created?

A Not that I'm aware of.

Q What, if anything, Dr. Carchman, does the analysis of the P53 material performed in this case tell you about where Mrs. Wiley's cancer might have started?

MR. MOTLEY: Excuse me, Your Honor, may I have that question back again, please.

You can read that question back.

MR. OHLEMEYER: I'll rephrase it. Let me withdraw it and rephrase it.

Q Let me ask you, tell me about the -- tell me what the data -- what, if anything, does the data that you reviewed with respect to this P53 analysis tell you about the type of -- can you associate the observations in this data with any particular type of cancer based upon the material found in this database?

A The only material that seems to have some

general feeling by the scientific community as being a very specific marker for a P53 mutation is aflatoxin.

Q Is a P53 mutation, and specifically a G to T transversion at codon 157, believed to be a hot spot or a fingerprint for lung cancer?

A Only as reported in the Denissenko test tube studies that they reported in Science.

Q What do you mean by that?

A When they did their study, they didn't use benzo(a)pyrene. They used a metabolite of benzo(a)pyrene, and they put it into dishes that had cells, various kinds of cells in it, and they added what comes out to be at least a million times higher levels of this material than anything in anybody's lung would ever see. So they didn't really look at benzo(a)pyrene. They looked at a metabolite, and they used heroic levels of the material.

I think the paper was published in '96. The reason I think it may have been published in '96 was that there were two

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other papers that appeared that year in the scientific literature.

One was a paper in Environmental Health Perspectives by Laskey and Silvergard that actually used what at the time was the current version of the IARC database. And a paper by Drs. Chen and Dr. Tilley in Mutation Research.

And two points to be made here. Number one, Laskey and Silvergard concluded that one had to be very careful when talking about hot spots. They really weren't sure what they meant. They said it would be -- I'm paraphrasing now. They said it would be nice if you can use a mutational change as a fingerprint for some event. But they said we don't know enough to be able to conclude that.

Number two, they said the so-called hot spots that people are seeing could be due to a number of factors, not the least of which is the tissue in which the mutation takes place.

So a particular chemical, benzo(a)pyrene, that may produce a mutation in the lung, may also produce a mutation in the liver. The P53 mutation that you see

could be totally different between the lung and the liver because each tissue has an environment that helps direct whatever is going to happen.

So they said it would be nice, in fact, it would be important if you can do it, but they basically said we're not there yet.

The Chen and Tilley paper took test tube in vitro work and they added compounds like the BPDE, which is the benzo(a)pyrene derivative metabolite that Denissenko used and they did a mutagenic assay.

Their conclusion was that you could not translate what you did in the test tube at these heroic levels to anything that you would see in an intact organism like a human being. They were saying be careful. It's interesting. And it is interesting what they saw. But what it means to you and me, they said, you have to be very careful.

And Laskey and Silvergard basically said you had to be careful when talking about hot spots as well.

Q So let me see if I can lead up to the question I want to ask you. The fact that

you have a mutation in P53 does or does not mean you've been exposed to benzo(a)pyrene?

A Does not.

Q The fact that you have a mutation in a P53 gene does or does not allow you to determine

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what type of cancer somebody has?
A I'm not sure I understand.
Q If you have a mutation in one of these codons, does that in and of itself tell you that you're looking at -- better question.
Are these mutations specific to certain types of cancers such as lung cancer?
A No. No.
Q So you can find the same types of mutations in other types of cancers.
A Yes.
Q Okay. And to analyze this material in a specific person, you do what's called a PCR test; right?
A That's correct.
Q And tell us what Dr. Cagle -- was it Dr. Cagle who did this test?
A He reported on the data, but I think he had it sent outside.
Q How many times were -- how many sequences

were run of this data as it relates to Mrs. Wiley's gene?
A What I was able to glean, just looking at the exons he looked at, there were at least 11 runs. 11 determinations.
Q Eleven sequences?
A Eleven PCR-type analyses.
Q And what were the results? What codons did they find or did he find mutations on?
A He found, on the 11th try, he found a mutation in 157. He also in other -- in the results from other runs did not find mutations in 157 but found mutations in at least two other codons. 139, I believe, and maybe 213. But 139 for sure. It's been a while since I've looked at the data.
Q Did they ever run a sequence, find a mutation, run it again and find the same mutation?
A I don't think so.
Q What, if anything, does that tell you about the observations or the data?
A I wouldn't want to do anything with this kind of information.
THE COURT: I didn't hear your

last.
A I would not want to do anything with information in which it took 11 trials, and I only saw the 157 on the 11th trial, and I saw other mutations on some of the other runs. That's not the way the assay, if it's done correctly, is supposed to report information.
As I said, if you looked in the literature at the people who do this for a living scientifically, they basically ask you to repeat what you've done at least once and confirm it. So they should have taken the 157 piece and repeated it again, but,

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for whatever reason, they either didn't do it or I didn't see the information.
Q So am I correct that the codon 157 occurs in exon 5?
A I think so.
Q How many analyses of exon 5 were conducted?
A A number.
Q More than one?
A I think so.
Q And was a mutation at codon 157 observed more than once?

A No.
Q How many analyses -- where is codon 213? Is that exon 6?
A I think it's 6, yes.
Q How many analyses were done on exon 6?
A I think several.
Q And were they ever able to repeat the observation of the mutation at codon 213?
A I don't -- I don't think so. I focused primarily on 157. And when I saw the problems that he had, the data had with 157, I didn't pay as much attention to the other changes which seemed to come and go as well.
Q Dr. Carchman, is a -- based on your background and your experience, your education in molecular biology, based upon the research you've done in connection with this issue, based upon your review of the database, that P53 database, is a -- can you tell us whether a mutation at codon 157 is a mutation that only occurs in lung cancers?
A It's not evident at all from the scientific literature, from the big IARC database, the answer would be no.
Q So it's a mutation that can be observed in

other types of tumors.
A Yes, it is.
Q Is it a mutation that is only associated with tumors that are believed to have some connection to benzo(a)pyrene?
A No.
Q And what other substances are associated with cancers in which these mutations have been observed?
A I think radon might be one such exposure.
Q Is that a piece of information that is also contained in that database?
A Yes, I think so.
Q How is it the information is organized in the database?
A It basically comes in a flat file. You can print out the whole -- the whole thing. And it has an Excel spreadsheet if you want to use it and you just type in questions and ask it to put things in certain fields. And you just hit a few keys and all of a sudden histograms can appear, or tabular-type graphs, as Mr. Ohlemeyer has presented, can

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appear. You can sift through this database and ask a whole variety of questions, which

was the purpose of setting up such a database.

Q Doctor, a different topic and finally this afternoon, let me ask you, you've been at Philip Morris now for how many years?

A A little over nine years.

Q And during that time, has Philip Morris been able to -- has Philip Morris attempted to prove that cigarette smoking does not cause cancer?

A Well, the question is -- cannot be addressed scientifically. You cannot prove a negative in science. What the hypothesis that you would ask is does cigarette smoking cause cancer. Does cigarette smoking cause -- that would be the hypothesis that you would test. You wouldn't test the other one that it doesn't because there would be no way to prove it.

Q And is there evidence to suggest that cigarette smoking might cause cancer?

A Yes.

Q What type of evidence?

A There's decades of epidemiological data. There's data which has analyzed the

chemistry of the smoke and the components within it. And for at least 43 of the components that have been identified in smoke, they are listed as either animal carcinogens or known human carcinogens. Within the 43, there are nine known human carcinogens.

And by known, what I mean is that some scientific body has sat down, sifted through all of the animal data, the epidemiology data, and drawn some conclusions. So there are at least nine things in smoke, mainstream smoke, that have been listed as known human carcinogens.

And the question is, having those things in smoke, what does that mean in terms of the smoker. It offers the possibility, if you have those things, that, indeed, there might be some kind of relationship.

Q And is and has there been an effort at the company during the time you've been there to reduce or remove those substances from smoke?

A Yes.

Q And how, in general terms, how successful has Philip Morris or anyone else been in removing those things from smoke?

A In general, the most effective way to date in terms of commercial products has been

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removing the tar. Because a lot of the materials that I'm talking about are found in the tar.

There is some other products that are out there now or being considered to be put out there one way or another that seems to further reduce some of these constituents.

Q With respect specifically to environmental tobacco smoke, how does the evidence -- is there evidence to suggest that environmental tobacco smoke is a possible cause of cancer in nonsmokers?

A There is evidence that has been drawn, the earlier cited EPA ETS risk assessment, the State of California has done a similar evaluation and drawn a conclusion. But the strongest body of data is derived from epidemiological studies in which people are asked questions about their ETS exposure.

And last week --

MR. MOTLEY: Excuse me, Your Honor, may I approach?

THE COURT: All right.

(Bench discussion)

THE COURT: Seems to be a difference of opinion. Rather than to ask you to leave and come back for another half hour or so, I think we'll take the evening break at this point. We'll continue and conclude his direct examination tomorrow morning, and then Mr. Motley will have an opportunity to ask him questions.

(Standard admonition)

THE COURT: I will see you tomorrow morning at 8:30. Leave your notes in the jury room. Good evening.

MR. CASSELL: All rise.

(Jury not present)

THE COURT: You may step down, Doctor.

MR. OHLEMEYER: Your Honor, if I may, do you mind, maybe we can just ask the witness questions.

THE COURT: That's not a bad idea.

MR. MOTLEY: I don't mind doing

that, Judge, but can --

THE COURT: We're going to take five minutes before we do that.

MR. MOTLEY: All right.

(A brief recess was taken.)

(Bench discussion)

THE COURT: See you in the morning.

(The proceedings were adjourned at 5:30 p.m. to be reconvened March 11, 1998, at 8:00 a.m.)

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INDEX OF EXAMINATION

DEFENDANTS' WITNESSES	DX	CX	RD	RC	RDC	RCC
PAUL LEVY		7293	7320	7338		
CHRISTOPHER COGGINS	7340	7417	7498	7516		
RICHARD CARCHMAN	7520					

INDEX OF PLAINTIFFS' EXHIBITS

EXHIBIT NOS.	RECEIVED	NOT RECEIVED
92	7442	
93	7457	
9973	7486	

INDEX OF DEFENDANTS' EXHIBITS

EXHIBIT NOS.	RECEIVED	NOT RECEIVED
CA1	7564	

http://legacy.library.ucsf.edu/tid/nw_05a00/pdf
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